No. 17-1484	
Title:	**Alex M. Azar, II, Secretary of Health and Human Services, Petitioner** **v.** **Allina Health Services, et al.**
Docketed:	April 30, 2018
Linked with 17A880	
Lower Ct:	United States Court of Appeals for the District of Columbia Circuit
Case Numbers:	(16-5255)
Decision Date:	July 25, 2017
Rehearing Denied:	November 29, 2017
Questions Presented	

DATE	PROCEEDINGS AND ORDERS
Feb 16 2018	Application (17A880) to extend the time to file a petition for a writ of certiorari from February 27, 2018 to March 29, 2018, submitted to The Chief Justice. **Main Document** **Proof of Service**
Feb 21 2018	Application (17A880) granted by The Chief Justice extending the time to file until March 29, 2018.
Mar 19 2018	Application (17A880) to extend further the time to file a petition for a writ of certiorari from March 29, 2018 to April 27, 2018, submitted to The Chief Justice. **Written Request** **Proof of Service**
Mar 22 2018	Application (17A880) granted by The Chief Justice extending the time to file until April 27, 2018.
Apr 27 2018	Petition for a writ of certiorari filed. (Response due May 30, 2018) **Proof of Service** **Petition** **Proof of Service** **Appendix**
May 23 2018	Motion to extend the time to file a response from May 30, 2018 to June 29, 2018, submitted to The Clerk. **Main Document**
May 24 2018	Motion to extend the time to file a response is granted and the time is extended to and including June 29, 2018.
Jun 19 2018	Brief of respondents Allina Health Services, et al. in opposition filed. **Main Document** **Certificate of Word Count** **Proof of Service**

Jul 03 2018	DISTRIBUTED for Conference of 9/24/2018.
Jul 05 2018	Reply of petitioner Alex M. Azar II, Secretary of Health and Human Services filed. (Distributed) **Proof of Service** **Main Document**
Sep 27 2018	Petition GRANTED limited to the following question: Whether 42 U. S. C. §1395hh(a)(2) or §1395hh(a)(4) required the Department of Health and Human Services to conduct notice-and-comment rulemaking before providing the challenged instructions to a Medicare Administrator Contractor making initial determinations of payments due under Medicare.
Oct 19 2018	Justice Kavanaugh is recused in this case.
Nov 13 2018	Brief of petitioner Alex M. Azar II, Secretary of Health and Human Services filed. **Certificate of Word Count** **Main Document**
Nov 13 2018	Joint appendix filed. **Proof of Service** **Main Document**
Nov 28 2018	SET FOR ARGUMENT ON Tuesday, January 15, 2019
Nov 30 2018	CIRCULATED
Dec 11 2018	Record requested from the U.S.C.A. District of Columbia Circuit.
Dec 13 2018	Brief of respondents Allina Health Services, et al. filed. (Distributed) **Main Document** **Certificate of Word Count** **Proof of Service**
Dec 14 2018	Record received from the U.S.C.A. Dist. of Columbia Circuit is electronic and located on PACER, with the exception of the transcript of the Oral Argument which is electronic.
Dec 20 2018	Brief amici curiae of Fourteen State and Regional Hospital Associations filed. (Distributed) **Main Document** **Certificate of Word Count** **Proof of Service**
Dec 20 2018	Brief amici curiae of American Hospital Association, et al. filed. (Distributed) **Main Document** **Certificate of Word Count** **Proof of Service**
Dec 20 2018	Brief amici curiae of 77 Hospitals and Southwest Consulting Associates filed. (Distributed) **Main Document** **Certificate of Word Count** **Proof of Service**
Dec 20 2018	Brief amici curiae of Catholic Health, et al. filed. (Distributed)

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Dec 20 2018	Brief amici curiae of American Medical Association and Medical Society of the District of Columbia filed. (Distributed) **Main Document** **Certificate of Word Count** **Proof of Service**	
Jan 08 2019	Reply of petitioner Alex M. Azar II, Secretary of Health and Human Services filed. (Distributed) **Proof of Service** **Main Document**	
Jan 15 2019	Argued. For petitioner: Edwin S. Kneedler, Deputy Solicitor General, Department of Justice, Washington, D. C. For respondents: Pratik A. Shah, Washington, D. C.	

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No.

In the Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Department of Health and Human Services (HHS) must utilize notice-and-comment rulemaking to promulgate rules, requirements, or statements of policy that "establish[] or change[]" a "substantive legal standard" governing payment for services under the Medicare Act, 42 U.S.C. 1395hh(a)(2). See 42 U.S.C. 1395hh(b)(1). The question presented is:

Whether Section 1395hh(a)(2) requires HHS to conduct notice-and-comment rulemaking before providing instructions to a Medicare Administrative Contractor that makes initial determinations of payments due under Medicare, when those instructions rest on a non-legally-binding administrative interpretation of a relevant statutory provision.

PARTIES TO THE PROCEEDING

Petitioner is Alex M. Azar II, in his official capacity of Secretary of Health and Human Services.

Respondents are Allina Health Services, doing business as United Hospital, Unity Hospital, and Abbott Northwestern Hospital; Florida Health Sciences Center, Inc., doing business as Tampa General Hospital; Montefiore Medical Center; Mount Sinai Medical Center of Florida, Inc., doing business as Mount Sinai Medical Center; New York Hospital Medical Center of Queens; New York Methodist Hospital; and New York and Presbyterian Hospital, doing business as New York Presbyterian Hospital Weill Cornell Medical Center.

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In the Supreme Court of the United States

No.

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the Secretary of Health and Human Services (Secretary), respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-18a) is reported at 863 F.3d 937. The opinion of the district court (Pet. App. 19a-44a) is reported at 201 F. Supp. 3d 94. The decisions of the Provider Reimbursement Review Board (Pet. App. 47a-61a, 62a-76a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on July 25, 2017. A petition for rehearing was denied on November 29, 2017 (Pet. App. 77a-80a). On February 21, 2018, the Chief Justice extended the time within

which to file a petition for a writ of certiorari to and including March 29, 2018. On March 22, 2018, the Chief Justice further extended the time to and including April 27, 2018. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant statutory and regulatory provisions are reproduced in the appendix to this petition. Pet. App. 81a-102a.

STATEMENT

1. This case concerns the scope of the specific notice-and-comment rulemaking requirements that the Department of Health and Human Services (Department or HHS) must follow under the Medicare Act, *i.e.*, Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.* The issue arises in the context of the Department's interpretation and calculation of one statutory component (the so-called "Medicare fraction") used to determine the total amount of payment that a hospital should receive under the Medicare program.

a. The Medicare Act, as relevant here, provides an annual payment to certain hospitals for providing inpatient hospital care to Medicare beneficiaries. 42 U.S.C. 1395ww(d); see 42 C.F.R. 412.1(a)(1). The Act provides an "additional payment"—known as a disproportionate share hospital (DSH) adjustment—to certain hospitals that "serve[] a significantly disproportionate number of low-income patients." 42 U.S.C. 1395ww(d)(5)(F)(i)(I). The standard for determining a hospital's eligibility for that payment is defined by the hospital's "disproportionate patient percentage" (DPP). 42 U.S.C. 1395ww(d)(5)(F)(v). A hospital is deemed to "serve[] a significantly disproportionate number of low

income patients" (and is thus entitled to a DSH payment) in a cost-reporting period if it has a DPP that meets or exceeds a specified level. *Ibid.*

The DPP, in turn, is the sum of two fractions expressed as percentages. 42 U.S.C. 1395ww(d)(5)(F)(vi). The first fraction—known as the Medicare fraction—is defined in part by a hospital's number of patient days during the relevant period that were attributable to patients who were both "entitled to benefits under [Medicare] part A" (which provides inpatient hospital insurance coverage) and entitled to supplemental security income (SSI) benefits. 42 U.S.C. 1395ww(d)(5)(F)(vi)(I); see 42 U.S.C. 1395c *et seq.* (Medicare Part A).[1] The second fraction, known as the Medicaid fraction, is separately defined in 42 U.S.C. 1395ww(d)(5)(F)(vi)(II), and includes patient days attributable to persons who, *inter alia*, "were not entitled to benefits under [Medicare] part A," *ibid.*

In 1997, Congress amended the Medicare Act by adding Part C, 42 U.S.C. 1395w-21 *et seq.*, which established the Medicare+Choice (M+C) program, later renamed the Medicare Advantage (MA) program.[2] Part C allows certain individuals to elect to receive benefits available under Part A and Part B through enrollment in a private healthcare plan known as a MA plan.

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[1] SSI benefits are available under Title XVI of the Social Security Act, 42 U.S.C. 1381 *et seq.*, "to financially needy individuals who are aged, blind, or disabled." *Bowen* v. *Galbreath*, 485 U.S. 74, 75 (1988).

[2] See Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (2003 Modernization Act), Pub. L. No. 108-173, § 201(a) and (b), 117 Stat. 2176 (42 U.S.C. 1395w-21 note) (establishing the Medicare Advantage program and providing that "any [Part C] reference to 'Medicare+Choice' is [now] deemed a reference to 'Medicare Advantage' and 'MA'").

42 U.S.C. 1395w-21(a)(1). In order to be enrolled under Medicare Part C, an individual must be "entitled to benefits under [Medicare] part A * * * and enrolled under [Medicare] part B." 42 U.S.C. 1395w-21(a)(3)(A).

The underlying interpretive issue in which the procedural notice-and-comment question presented in this case arises is whether a patient who receives coverage for his or her Medicare Part A benefits through a private healthcare plan under Medicare Part C is a patient "entitled to benefits under [Medicare] part A" for purposes of determining a hospital's Medicare fraction under 42 U.S.C. 1395ww(d)(5)(F)(vi)(I).

b. HHS administers the Medicare program through the Centers for Medicare & Medicaid Services (CMS). CMS, in turn, contracts with private entities known as Medicare Administrative Contractors (MACs)—formerly called fiscal intermediaries—that "act on behalf of CMS in carrying out certain administrative responsibilities." 42 C.F.R. 421.5(b); see 42 U.S.C. 1395kk-1(a)(1).[3] As relevant here, CMS contracts with MACs to determine in the first instance "the amount of the payments required pursuant to [the Medicare Act] to be made to providers of services." 42 U.S.C. 1395kk-1(a)(4)(A). Such contractors, like CMS's own personnel, are "required to follow Federal laws, regulations and [CMS] manual instructions" when performing such functions on behalf of CMS. 74 Fed. Reg. 65,296, 65,312 (Dec. 9, 2009).

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[3] "[A]ny reference to a fiscal intermediary or carrier under * * * [the Medicare Act] (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such [Act])" is now "deemed a reference to a medicare administrative contractor." 2003 Modernization Act § 911(e), 117 Stat. 2386 (42 U.S.C. 1395kk-1 note).

i. In order to receive payment for providing inpatient hospital services to Medicare beneficiaries, a hospital must submit an annual cost report to its MAC. 42 C.F.R. 405.1801(b)(1). After receiving the cost report, the MAC determines "the total amount of reimbursement due the provider" for the relevant cost-reporting period and issues a Notice of Program Reimbursement containing its determination. 42 C.F.R. 405.1803(a) and (a)(2).

A MAC, however, lacks the information necessary to determine a hospital's Medicare fraction. That is because the Medicare fraction is defined in part by hospital services furnished to patients who were both "entitled to benefits under [Medicare] part A" and "entitled to [SSI] benefits," 42 U.S.C. 1395ww(d)(5)(F)(vi)(I), and data from the Social Security Administration's "SSI file" are needed to make the calculation. 51 Fed. Reg. 16,772, 16,777 (May 6, 1986); see Pet. App. 105a ¶ 7. CMS therefore itself calculates the Medicare fraction for each hospital, 42 C.F.R. 412.106(b)(2); 42 C.F.R. 412.106(b)(2) (2003), and makes the calculated fractions available to the MACs. Each MAC then independently calculates a hospital's Medicaid fraction and adds both fractions to determine the hospital's DPP and its eligibility for (and the proper amount of) a DSH payment as part of the hospital's overall Medicare reimbursement for the cost year. See 42 C.F.R. 412.106(b)(4)-(5), (c), and (d); 42 C.F.R. 412.106(b)(4)-(5), (c), and (d) (2003).

ii. A provider may file an administrative appeal to the Provider Reimbursement Review Board (PRRB) from the MAC's final determination or its failure to render a final determination within 12 months. 42 U.S.C. 1395*oo*(a) and (d); 42 C.F.R. 405.1835(c). In rendering its decision, the Board need only apply the provisions of

the Medicare Act, agency regulations, and formal CMS Rulings issued by the CMS Administrator. 42 C.F.R. 405.1867. Provisions in CMS's manuals and other interpretive rules thus do not bind the Board. *Ibid.*[4]

If the Board determines that it lacks "authority to decide" a relevant "question of law or regulations" (or if it fails to issue a decision within 30 days of a provider's request for such a determination), the provider may seek judicial review of the "action of [the MAC]" that implicates that question. 42 U.S.C. 1395*oo*(f)(1); see 42 C.F.R. 405.1842(a) and (h), 405.1875(a)(2)(iii). Otherwise, after the PRRB issues its final decision on the merits, the Secretary (acting through the CMS Administrator) may within 60 days reverse, affirm, or modify that decision. 42 U.S.C. 1395*oo*(f)(1); see 42 C.F.R. 405.1875.

iii. The final agency decision is then subject to review in district court under the standards for review in the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, 701 *et seq.* See 42 U.S.C. 1395*oo*(f)(1).

c. Before 2004, CMS did not count a hospital's Medicare Part C patient days when calculating the Medicare fraction for each hospital. See *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 15-16 (D.C. Cir. 2011). That practice was not based on notice-and-comment rulemaking or any formal agency guidance. In 2003, after "receiv[ing] questions whether patients enrolled in an M+C Plan should be counted in the Medicare fraction," CMS chose to address that question through the notice-and-comment process, proposing a rule that would have excluded Part C patient days from that fraction. 68 Fed. Reg. 27,154, 27,208 (May 19, 2003).

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[4] The Board will give great weight to, but need not follow, interpretive rules. 42 C.F.R. 405.1867.

In 2004, after considering public comments—several of which disagreed with its earlier proposal—CMS concluded that Part C patients are "entitled to benefits under [Medicare] part A" within the meaning of the Medicare-fraction provision, 42 U.S.C. 1395ww(d)(5)(F)(vi). See 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004). CMS therefore announced that it would count Part C patient days in the Medicare fraction. *Ibid.*[5]

A district court (in a separate case) later vacated that 2004 final rule based on its determination that it was not a logical outgrowth of CMS's 2003 proposal, and it ordered CMS to "affirmatively count Part C days under the Medicaid fraction"—rather than under the Medicare fraction—for the FY2007 cost reports that were at issue in that case. See *Allina Health Servs.* v. *Sebelius*, 746 F.3d 1102, 1105, 1111 (D.C. Cir. 2014) (describing decision). The D.C. Circuit affirmed the district court's holding that the 2004 final rule was not a logical outgrowth of the 2003 proposal, *id.* at 1107-1109, but vacated its requirement that CMS count Part C days in the Medicaid fraction, explaining that "the Secretary might achieve the same result [reached in the vacated rule] through adjudication" of the FY2007 cost reports at issue in that case, *id.* at 1111.[6] On remand, the CMS

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[5] CMS inadvertently did not amend its regulations to reflect the 2004 final rule until 2007. 72 Fed. Reg. 47,130, 47,384, 47,411 (Aug. 22, 2007) (amending 42 C.F.R. 412.106(b)(2)(i)(B) and (iii)(B)).

[6] Despite its disagreement with the district court's view that its final rule was not the logical outgrowth of its proposed rule, cf. *Long Island Care at Home, Ltd.* v. *Coke*, 551 U.S. 158, 174-175 (2007), HHS instituted new notice-and-comment rulemaking "in an abundance of caution" while its appeal of that ruling was pending. 78 Fed. Reg. 50,496, 50,614-50,615 (Aug. 19, 2013). In 2013, HHS promulgated a final rule in which the agency again concluded that Part C patients "are 'entitled to benefits under part A'" within the

Administrator, acting for the Secretary, interpreted the Medicare-fraction statute as part of the agency's adjudication of the plaintiff-hospitals' FY2007 cost reports and concluded that Part C patient days are properly counted in the Medicare fraction. *Allina Health Servs.* v. *Burwell*, No. 2010-D38-R, at 24-46 (CMS Adm'r. 2015), judicial review pending, No. 1:16-cv-150 (D.D.C. filed Jan. 29, 2016).[7]

2. a. Meanwhile, as a result of the D.C. Circuit's decision affirming vacatur of CMS's 2004 final rule, there was no controlling CMS determination whether Part C patient days were to be included in the Medicare fraction. Yet CMS was still obligated to determine annual Medicare fractions for individual hospitals in order to enable MACs to determine each hospital's appropriate Medicare reimbursement. See Pet. App. 105a ¶ 6.

That was the state of affairs in June 2014, when CMS calculated Medicare fractions for FY2012 for hospitals nationwide (including hospitals operated by respondents) and published those fractions in a spreadsheet posted on its website. Pet. App. 5a-6a, 24a. The agency did not calculate those FY2012 Medicare fractions by "rel[ying] on the vacated [2004] rule." *Id.* at 105a ¶ 7; see *id.* at 30a-31a. But the spreadsheet included a note explaining that the "[c]alculations * * * includ[ed] MA

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meaning of the Medicare-fraction statute. *Id.* at 50,614-50,615, 50,620. The 2013 final rule applies prospectively "for FY 2014 and subsequent years." *Id.* at 50,619. Hospitals have challenged the 2013 final rule in a separate civil action that remains pending. See Second Am. Compl. ¶¶ 5, 58-62, *Florida Health Scis. Ctr.* v. *Azar*, No. 17-cv-1751 (D.D.C. Mar. 13, 2018).

[7] The Administrator's decision on remand is available at https://www.cms.gov/Regulations-and-Guidance/Review-Boards/OfficeAttorneyAdvisor/OAA-Decisions-Items/2010-D38-R.html.

[*i.e.*, Part C] Claims Submissions." See CMS, *Disproportionate Share Hospital (DSH)* (providing FY2012 fraction spreadsheet in "DSH Adjustment and 2011-2012 File").[8] That notation reflected CMS's "decision * * * to include Part C days" in calculating the FY2012 Medicare fractions based on the agency's independent "'interpretation of the statute'" as including "'Part C days * * * in the Medicare fraction.'" Pet. App. 33a (citation omitted); see *id.* at 5a-6a.

b. Respondents challenged CMS's calculation of the Medicare fractions by seeking administrative review by the PRRB. See Pet. App. 47a-48a, 62a-63a. The Board concluded that it lacked authority to decide that challenge and granted respondents' request for expedited judicial review. *Id.* at 57a-58a, 72a-73a.

3. a. Respondents accordingly filed this action for judicial review in district court. See Pet. App. 25a-26a. Among other things, respondents argued that the Medicare Act's rulemaking provision in 42 U.S.C. 1395hh required that the agency engage in notice-and-comment rulemaking before it could base its calculations of respondents' FY2012 Medicare fractions on its interpretation of the Act. See Pet. App. 35a-36a.

Section 1395hh grants the Secretary authority to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [the Medicare Act]." 42 U.S.C. 1395hh(a)(1). Section 1395hh(a)(2) further provides:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard

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[8] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html.

> governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [the Medicare Act] shall take effect unless it is promulgated by the Secretary by regulation under [Section 1395hh(a)(1)].

42 U.S.C. 1395hh(a)(2).

Section 1395hh(b)(1), in turn, provides that before "issuing in final form any regulation under [Section 1395hh(a)]," the Secretary must publish "notice of the proposed regulation in the Federal Register" and provide a public comment period of "not less than 60 days." 42 U.S.C. 1395hh(b)(1). That notice-and-comment requirement is subject to certain exceptions, 42 U.S.C. 1395hh(b)(2), including one for circumstances in which the APA's good-cause exception, 5 U.S.C. 553(b)(B), would not require notice-and-comment rulemaking under the APA. 42 U.S.C. 1395hh(b)(2)(C).

Finally, Section 1395hh(a)(4) provides that "[i]f the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation." 42 U.S.C. 1395hh(a)(4).

b. The district court granted summary judgment to the government. Pet. App. 19a-44a. The court held that CMS's calculation of the FY2012 Medicare fractions by "includ[ing] Part C days," *id.* at 33a, did not require notice-and-comment rulemaking. *Id.* at 34a-36a. The court concluded that Section 1395hh does not apply to

"'interpretive rules'" and that the agency's "interpretation of the DSH statute" in the course of calculating the Medicare fractions to be furnished to MACs "is not a 'rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard'" within the meaning of Section 1395hh(a)(2). *Id.* at 35a-36a (citations omitted).

The district court then rejected respondents' substantive challenge to the agency's interpretation of the Medicare-fraction statute, Pet. App. 39a-44a, holding that the agency had permissibly concluded that "patients enrolled in Part C continue to be 'eligible' for Part A" within the meaning of that provision, *id.* at 44a.

4. The court of appeals reversed and remanded. Pet. App. 1a-18a. As relevant here, the court held that Section 1395hh required HHS to conduct notice-and-comment rulemaking before providing MACs with CMS's calculation of each respondents' FY2012 Medicare fractions reflecting the agency's interpretation of the statute. *Id.* at 11a-18a.

a. The court of appeals first determined that CMS's calculation of the FY2012 Medicare fractions for its MACs was, "at the very least, a 'requirement'" under Section 1395hh(a)(2). Pet. App. 12a-13a. The court reasoned that "[f]iscal intermediaries are *commanded* to use HHS's Medicare fractions in calculating [DSH] adjustment amounts" and "are therefore *required* to include Part C days in their calculations." *Ibid.*

The court of appeals next held that CMS had "established" a "'substantive legal standard'" within the meaning of Section 1395hh(a)(2) by including "Part C days in the fiscal year 2012 Medicare fractions" it furnished to MACs. Pet. App. 13a-14a. The court rested that holding on a dictionary definition of "'[s]ubstantive

law' [as] law that 'creates, defines, and regulates the rights, duties, and powers of parties.'" *Ibid.* (citation omitted). The court concluded that the agency's "2012 Medicare fractions" qualified as a "substantive legal standard" because, in the court's view, they "define the scope of hospitals' legal rights to payment for treating low-income patients." *Id.* at 14a.

The court of appeals also concluded that the inclusion of Medicare Part C days in the FY2012 Medicare fractions "change[d]" a "substantive legal standard" within the meaning of Section 1395hh(a)(2). Pet. App. 13a. The court reasoned that, before 2004, CMS's "practice was to *exclude* Part C days from Medicare fractions," that the pre-2004 practice "remains the baseline practice," and that the agency's inclusion of Part C days for FY2012 was "therefore a change from prior practice." *Ibid.*

b. The court of appeals rejected the government's contention that Section 1395hh's notice-and-comment requirement for regulations establishing or changing a "substantive legal standard," 42 U.S.C. 1395hh(a)(2), does not apply to "interpretive rules." Pet. App. 15a-17a. The court reasoned that Section 1395hh uses "different language" than the APA's rulemaking provision and, unlike the APA, does not expressly "include an exception for interpretive rules." *Id.* at 15a-16a. The court also noted that Section 1395hh(b)(2) "incorporates the APA's 'good-cause' exception" in 5 U.S.C. 553(b)(B), which in the court's view showed that "Congress knew how to incorporate the APA's notice-and-comment exceptions * * * when it wanted to." Pet. App. 16a. The court acknowledged that its holding that Section 1395hh(a)(2) applies to interpretive rules conflicts with decisions of "several other courts of appeals," but stated

that it respectfully disagreed with those decisions. *Id.* at 17a.[9]

c. Finally, the court of appeals held that "even if HHS were correct" that Section 1395hh(a)(2) does not apply to "interpretive rules," Section 1395hh(a)(4) would separately require notice-and-comment rulemaking. Pet. App. 17a-18a. Because the court in an earlier case had vacated HHS's 2004 rule announcing its interpretation of the Medicare fraction on the ground that the final rule was "'not a logical outgrowth of the proposed rule,'" *id.* at 18a (citation omitted); see p. 7, *supra*, the court concluded that Section 1395hh(a)(4) "applies with full force" and requires a "'further opportunity for public comment and a publication of the provision again as a final regulation' before HHS could reimpose the rule," Pet. App. 18a (citation omitted). CMS, the court added, "could not circumvent this requirement by claiming that it was acting by way of adjudication rather than rulemaking," because Section 1395hh(a)(4) "says that the vacated rule may not 'take effect' at all until there has been notice and comment." *Ibid.*

REASONS FOR GRANTING THE PETITION

It is extremely important that agencies rigorously observe applicable procedural requirements, to provide the requisite notice to regulated parties. Within this specific and complex statutory scheme, however, the relevant Medicare rulemaking provision applies only to regulations that establish or change a "substantive legal

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[9] In light of its holding that Section 1395hh requires notice-and-comment rulemaking even for interpretive rules, the court of appeals stated that it "need not decide" if HHS's inclusion of Part C days in the FY2012 Medicare fractions it furnished to MACs was an "interpretive rule." Pet. App. 15a.

standard." 42 U.S.C. 1395hh(a)(2). Interpreting that provision, the D.C. Circuit held that HHS must conduct notice-and-comment rulemaking in order to provide internal instructions (in the form of FY2012 Medicare fractions) to its Medicare Administrative Contractors that are based on an interpretation of the Medicare Act. As the D.C. Circuit acknowledged, the decisions of other courts of appeals reflect the view that instructions from HHS to its Medicare Administrative Contractors about Medicare fractions lack the force and effect of law, and thus do not qualify as a "substantive legal standard" under Section 1395hh(a)(2). See Pet. App. 17a. The D.C. Circuit's contrary decision would significantly impair HHS's ability to administer annual Medicare reimbursements through the MACs that act on its behalf. It would also impose significant costs on the government. Just with respect to the Medicare-fraction issue in this case, the decision below affects between $3 and $4 billion in Medicare funding. This Court's review is therefore warranted.

A. The Decision Below Creates A Circuit Split By Holding That Section 1395hh's Notice-And-Comment Procedures Apply To Interpretive Rules

1. As the D.C. Circuit in this case acknowledged, its holding departs from the decisions of the other courts of appeals that have considered the issue, see Pet. App. 17a, which have held that Section 1395hh(a)(2) does not apply to interpretive rules. The First Circuit, for instance, has determined that, although Section 1395hh(a)(2)'s application to "substantive legal standard[s]" "phrases the distinction between substantive and interpretive rules slightly differently from the APA," Section 1395hh nevertheless exempts "interpretive rules" and is fairly understood to "duplicate the

APA on this score." *Warder* v. *Shalala*, 149 F.3d 73, 79 & n.4 (1998), cert. denied, 526 U.S. 1064 (1999). The Ninth Circuit has similarly held that CMS manual provisions are "interpretive rules" under the APA that do not have the force of law, and that Section 1395hh(a)(2), like the APA, does not require notice-and-comment rulemaking for "interpretive rules." *Erringer* v. *Thompson*, 371 F.3d 625, 632-633 (2004); see *id.* at 630. The Eighth Circuit has adopted the same understanding of Section 1395hh. *Baptist Health* v. *Thompson*, 458 F.3d 768, 776 & n.9 (2006). The Eighth Circuit explained that although Section 1395hh(a)(2) applies to certain changes to a "'substantive legal standard,'" it does not apply to an agency "change [in] interpretation" because the statute does not require rulemaking procedures "greater than those established by the APA." *Ibid.* (citation omitted).

2. Consistent with the decisions of other courts of appeals, HHS has understood that Congress's choice of the phrase "substantive legal standard" reflects its intent to apply rulemaking procedures only to "substantive" regulations that have "legal" force and establish "standards" governing Medicare reimbursement, benefits, and eligibility determinations.

a. The APA's notice-and-comment requirements, 5 U.S.C. 553(b) and (c), apply to what have long been known as "substantive rules." See *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 313, 315 (1979). Well before Congress enacted Section 1395hh's rulemaking requirements for "substantive legal standard[s]" under Medicare, 42 U.S.C. 1395hh(a)(2), it was "well established" that properly promulgated "substantive agency regulations have the 'force and effect of law.'" *Chrysler Corp.*, 441 U.S. at 295. A "substantive rule—or a 'legislative-

type rule'"—has binding legal force because it has been promulgated pursuant to a congressional grant of "quasi-legislative authority" and "conform[s] with [the] procedural requirements" that Congress has provided for its promulgation, which normally include the APA's notice-and-comment requirements. *Id.* at 302-303; see *id.* at 313.

By contrast, the APA provides that, unless "notice or hearing is required by statute," its notice-and-comment provision "does not apply * * * to interpretative rules." 5 U.S.C. 553(b)(A). An "interpretative rule" serves a function significantly different from that of a substantive rule. See *Perez* v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1204 & n.1 (2015). "[I]nterpretive rules" are "'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'" *Ibid.* (quoting *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995)); accord *Chrysler Corp.*, 441 U.S at 302 n.31 (quoting U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 30 n.3 (1947) (*1947 APA Manual*)). And significantly for present purposes, unlike "substantive" rules, "'interpretive rules' * * * do *not* have the force and effect of *law*," and courts therefore are not required to give them "the binding effect of law." *Chrysler Corp.*, 441 U.S at 302 n.31, 315 (emphases added); accord *Mortgage Bankers Ass'n*, 135 S. Ct. at 1208 (relying on the "longstanding recognition" that "interpretive rules do not have the force and effect of law"); *Guernsey Mem'l Hosp.*, 514 U.S. at 99.

b. Against the backdrop of the APA's governing legal framework, Congress enacted a notice-and-comment procedure, 42 U.S.C. 1395hh(b)(1), that applies to rules, requirements, and other statements of

policy that establish or change certain "substantive legal standard[s]" under the Medicare Act. 42 U.S.C. 1395hh(a)(2). The decisions of other courts of appeals are consistent with the view that, in adding the notice-and-comment rulemaking requirement for "substantive legal standards," Congress would have understood that "[t]he central distinction among agency regulations found in the APA is that between 'substantive rules' on the one hand and 'interpretive rules' * * * on the other." *Chrysler Corp.*, 441 U.S. at 295. And Congress likewise can be presumed to have known the "well established" principle that "substantive agency regulations" carry the "'force and effect of law,'" but that "'interpretive rules' * * * do not." *Id.* at 295, 302 n.31 (citing, *e.g.*, *1947 APA Manual* 30 n.3). A quintessential function of "substantive rules," moreover, has long been recognized to be "defining *standards*" under a governing statute that carry the "force and effect of law." *1947 APA Manual* 13 n.5, 30 n.3 (emphasis added).[10]

Those same principles are embodied in Congress's decision to apply Section 1395hh(a)(2) only to "substantive legal standards" governing benefits, payment, and eligibility under Medicare. Nothing in Section 1395hh suggests that Congress intended to apply a new notice-and-comment requirement for subsidiary "interpretive rules." Indeed, the function played by an interpretive rule is incompatible with the textual scope of Section 1395hh(a)(2). An "interpretive rule" by its nature does

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[10] This Court has repeatedly found the Attorney General's 1947 manual interpreting the APA to be a persuasive construction of the APA. See, *e.g.*, *Norton* v. *Southern Utah Wilderness Alliance*, 542 U.S. 55, 63-64 (2004) (citing cases); *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 546 (1978).

not "establish[] or change[]" a "substantive legal standard," 42 U.S.C. 1395hh(a)(2). Such a rule simply announces "the agency's *construction* of the statutes and rules which it administers." *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204 (emphasis added; citation omitted). As such, the view that "an interpretive rule *changes* the [legal provision] it interprets" cannot be "reconcile[d] with the longstanding recognition that interpretive rules do *not* have the force and effect of law." *Id.* at 1208 (emphases added).

3. The court of appeals also held that CMS's calculation of FY2012 Medicare fractions constituted a type of "'requirement'" under Section 1395hh(a)(2) triggering notice-and-comment procedures because the agency directed that MACs "use [those] Medicare fractions in calculating [DSH] adjustment amounts" and thereby "*required* [the MACs] to include Part C days in their calculations." Pet. App. 12a-13a. HHS's practice thus reflects the view that Section 1395hh(a)(2) refers to requirements for providers, not instructions to MACs that make an initial reimbursement determination on CMS's behalf that providers may appeal. The D.C. Circuit has explained that "[i]t is irrelevant whether an HHS directive * * * requir[es] [private entities], as a condition of entering into a contract with HHS" to assist in administering the Medicare program, to follow the agency's instructions when they make determinations on the agency's behalf. *American Hospital Ass'n* v. *Bowen*, 834 F.2d 1037, 1049 (D.C. Cir. 1987). According to that opinion, "focusing on the impact upon [such private entities] of * * * HHS directives" "fail[s] to take heed of the critical difference between [those entities] and hospitals" in this context. *Ibid.*; see *ibid.* (noting the anomaly that would result if "HHS cannot reach

through its contracting agents the same result that it could surely reach itself by using its own employees").

B. The Decision Below Undermines HHS's Ability To Administer The Annual Medicare Reimbursement Process

1. The court of appeals' decision threatens to undermine HHS's ability to administer the Medicare Program in a workable manner. The Medicare program is a "massive, complex health and safety program * * * embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations." *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). Those provisions setting the substantive legal standards for reimbursement and other matters in this extraordinarily complex area of law contain myriad ambiguities that must be resolved, at least as an initial matter, by CMS in its administration of the Medicare program. Agency interpretations such as those in the Provider Reimbursement Manual (PRM) thus set forth CMS's views on questions of Medicare reimbursement for the benefit of providers and promote national uniformity in the administration of the Medicare program by guiding MACs in the initial reimbursement determinations they make on behalf of the agency.

Because MACs are "required to follow * * * [CMS] manual instructions" when performing functions on behalf of CMS, 74 Fed. Reg. at 65,312,[11] the court of ap-

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[11] CMS's contracts with MACs also specify that the contractor must comply with "applicable laws, regulations, Medicare manuals, and CMS requirements." See, *e.g.*, Fed. Bus. Opportunities, *Part A/B Medicare Administrative Contractor*, Solicitation 1, No. HHSM-500-2017-RFP-0016, J.01 SOW, § C.1.1, at 19, https://www.fbo.gov/index?s=opportunity&mode=form&id=f7d62fc4ab22c66

peals' decision undermines that longstanding administrative framework by allowing invalidation of Medicare reimbursement determinations that follow such interpretations—not because they are substantively wrong, but because CMS did not go through notice-and-comment rulemaking before issuing such interpretive materials to its own agents. Converting the agency's non-binding manuals and other interpretive materials into regulations requiring notice and comment would jeopardize the flexibility needed in light of Medicare's complex and frequently changing statutory context and administrative developments. The notice-and-comment process can be "long and costly" and "often requires many years and tens of thousands of person hours to complete." Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretative Rules*, 52 Admin. L. Rev. 547, 550-551 (2000); see U.S. Gov't Accountability Office, GAO-09-205, *Federal Rulemaking* 5, 19 (2009) (case study finding average of over four years to complete notice-and-comment rulemaking and that some "rules that were not major took nearly as long or longer to be published").

2. The court of appeals concluded that CMS's inclusion of Part C days in its calculation of the FY2012 Medicare fractions furnished to its MACs "change[d] a substantive legal standard," 42 U.S.C. 1395hh(a)(2), because it reflected a "change from [the agency's] prior practice" of "*exclud[ing]* Part C days from Medicare fractions." Pet. App. 13a. But if the agency's calculation of the FY2012 fractions was invalid because it "change[d]" a substantive legal standard without

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notice-and-comment rulemaking, then the agency's earlier, pre-2004 practice of excluding Part C days was also invalid because that practice "establishe[d] * * * [the] substantive legal standard," 42 U.S.C. 1395hh(a)(2), that the FY2012 fractions purportedly "changed."[12]

Under the D.C. Circuit's rationale, HHS could not now even follow its pre-2004 practice, because that practice would itself establish a "substantive legal standard" and thus could not "take effect," 42 U.S.C. 1395hh(a)(2), without notice-and-comment rulemaking, 42 U.S.C. 1395hh(b)(1). And under that rationale, CMS could not have properly calculated *any* Medicare fractions for *any* hospital after the 1997 enactment of Medicare Part C, notwithstanding its continuing obligation to do so. Fulfilling that obligation required the agency to apply *some* interpretation of the Medicare-fraction statute to decide whether to count Part C days, but no such interpretation could be applied, under the logic of the decision below, without notice-and-comment rulemaking. That anomalous result would prohibit the agency from taking the actions needed for the MACs to process annual Medicare reimbursement requests when faced with any of the myriad statutory or regulatory ambiguities that arise under that program.

3. The court of appeals held that even if Section 1395hh(a)(2) would not have itself required notice-and-comment rulemaking before CMS furnished respondents' Medicare fractions to its MACs for the FY2012

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[12] This Court recently corrected a similar error by the D.C. Circuit in the APA rulemaking context. See *Mortgage Bankers Ass'n*, 135 S. Ct. at 1206 (rejecting conclusion that notice-and-comment rulemaking is required to "change" an agency interpretive rule where the agency could establish the rule without a notice-and-comment process) (citation omitted).

cost year, Section 1395hh(a)(4) would have still "required notice and comment" because HHS's 2004 final rule that would have required inclusion of Part C days in the Medicare fraction "'was not a logical outgrowth of the [2003] proposed rule.'" Pet. App. 17a-18a (citation omitted). But other courts have not concluded that Section 1395hh(a)(4), which addresses the consequences of the invalidation of a binding "substantive" rule, requires notice-and-comment rulemaking where Section 1395hh would not require such rulemaking for a (non-binding) interpretive action by CMS in the first place.

The court of appeals reasoned that the agency "could not circumvent [Section 1395hh(a)(4)'s] requirement by claiming that it was acting by way of adjudication rather than rulemaking." Pet. App. 18a. Agency adjudication, however, is an established method for resolving interpretive issues. Indeed, HHS has long "relie[d] upon an elaborate adjudicative structure"—which "includes the right to review by the [PRRB], and, in some instances, the Secretary, as well as judicial review in federal district court of final agency action"—to resolve "particular reimbursement details not addressed by [notice-and-comment] regulations." *Guernsey Mem'l Hosp.*, 514 U.S. at 96. Such a "choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC* v. *Chenery Corp.*, 332 U.S. 194, 203 (1947); see *Guernsey Mem'l Hosp.*, 514 U.S. at 96-97 (holding that HHS's mode of addressing Medicare reimbursement determinations "by both rulemaking and adjudication is * * * a proper exercise of [its] statutory mandate"). The decisions of other courts of appeals are consistent with the view that if Section

1395hh(a)(2) does not require notice-and-comment rulemaking for CMS to announce publicly its own non-binding understanding of the Medicare-fraction statute, the agency should not be prohibited from providing calculations to the MACs based on an interpretation of the substantive legal standard in the Medicare-fraction statute when such an interpretation is necessary to adjudicate a provider's claim for Medicare reimbursement. That agency understanding binds neither the administrative bodies that review a MAC's reimbursement decision, see 42 C.F.R. 405.1867, nor the courts on judicial review.

4. The adverse impact of the D.C. Circuit's ruling is particularly significant because universal venue lies in the District of Columbia over Medicare actions by providers. See 42 U.S.C. 1395*oo*(f)(1). Moreover, HHS has informed this Office that the particular issue in this case concerning the proper interpretation of the Medicare-fraction statute alone implicates between $3 and $4 billion in reimbursement for FY2005 through FY2013.[13] The significant financial stakes in this particular context underscore that certiorari is warranted because of the significant and ongoing adverse effect of the court of appeals' decision on the administration of the Medicare program.

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[13] The agency's 2013 final rule, which by its terms applies from FY2014 onwards, should limit the prospective significance of the court of appeals' decision in the particular context of whether to include Part C days in the Medicare fraction if that rule is upheld in the ongoing judicial review. See p. 8 n.6, *supra*.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APRIL 2018

No.

In the Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 16-5255

ALLINA HEALTH SERVICES, DOING BUSINESS AS UNITED HOSPITAL, DOING BUSINESS AS UNITY HOSPITAL, DOING BUSINESS AS ABBOTT NORTHWESTERN HOSPITAL, ET AL., APPELLANTS

v.

THOMAS E. PRICE, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, APPELLEE

Argued: May 11, 2017
Decided: July 25, 2017

Appeal from the United States District Court for the District of Columbia (No. 1:14-cv-01415)

Before: HENDERSON, KAVANAUGH, and MILLETT, *Circuit Judges.*

Opinion for the Court filed by *Circuit Judge* KAVANAUGH.

KAVANAUGH, *Circuit Judge*: Several hospitals have challenged the formula used by the Department of Health and Human Services for calculating certain Medicare reimbursement adjustments for fiscal year 2012. As relevant here, the hospitals argued before the District

Court that HHS violated the Medicare Act by changing the reimbursement adjustment formula without providing the public with notice and opportunity for comment.

The District Court ruled that HHS did not violate the Medicare Act's procedural requirements. The District Court reasoned that (i) the Medicare Act incorporates the Administrative Procedure Act's exception to notice-and-comment rulemaking for interpretive rules and (ii) HHS's issuance of the reimbursement adjustment formula here constituted an interpretive rule. The District Court granted summary judgment to HHS.

We disagree with the District Court. We conclude that HHS violated the Medicare Act when it changed its reimbursement adjustment formula without providing notice and opportunity for comment. We reverse the judgment of the District Court and remand for proceedings consistent with this opinion.

I

A

Through the Medicare program, the Federal Government provides health insurance to Americans who are 65 or older, as well as to disabled Americans. *See generally* Social Security Amendments of 1965, Pub. L. No. 89-97, sec. 102, 79 Stat. 286, 291-332 (codified as amended at 42 U.S.C. § 1395 *et seq.*). The Department of Health and Human Services administers and oversees Medicare. Patients can obtain insurance under different Medicare "parts." Two of those parts are relevant here. Medicare Part A provides Medicare enrollees with government-administered health insurance through which the Government makes direct payments to hospitals for healthcare services provided. *See*

42 U.S.C. §§ 1395c to 1395i-5. Part C provides enrollees with government-subsidized enrollment in private insurance plans. *See id.* §§ 1395w-21 to 1395w-29.

HHS contracts with companies known as fiscal intermediaries to reimburse healthcare service providers for services rendered to Medicare Part A patients. Fiscal intermediaries make initial payments to hospitals for a given cost year. Those initial payments are based on estimates of the hospitals' actual costs. The initial payments are later adjusted based on providers' actual cost reports.

A provider who disagrees with a fiscal intermediary's reimbursement or adjustment decision may appeal that decision to the Provider Reimbursement Review Board within HHS. *See* 42 U.S.C. § 1395*oo*. The Board may affirm, modify, or reverse the fiscal intermediary's decision. *Id.* § 1395*oo*(d). But importantly, the Board does not have the authority to declare statutes or regulations invalid. *See Bethesda Hospital Association v. Bowen*, 485 U.S. 399, 406 (1988); 42 C.F.R. § 405.1842(f)(2)(ii).

As relevant here, the Medicare Act authorizes reimbursement adjustments in order to increase payments to hospitals that treat a disproportionately high number of low-income patients. *See* 42 U.S.C. § 1395ww(d)(5)(F)(i)(I). That adjustment is known as the "disproportionate share hospital adjustment." The adjustment is calculated for each hospital by adding two fractions that together approximate the proportion of low-income patients treated at that hospital over a certain time period. *See id.* § 1395ww(d)(5)(F)(vi). HHS calculates and publishes one of those fractions—the Medicare fraction—for each hospital in the Nation every year. HHS requires the fiscal intermediaries to

use HHS's published Medicare fractions in calculating each hospital's final reimbursement adjustment. *See* 42 C.F.R. § 412.106(b)(2), (5).

Among other things, the Medicare fraction incorporates the number of each hospital's patient days for patients "entitled to benefits under part A" of Medicare. 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I). The meaning of that phrase has been the subject of much debate (and litigation). The dispute is over whether the phrase "entitled to benefits under Part A" should be read to refer not only to Part A enrollees, but also to patients enrolled in a Part C plan.

For reasons that are beyond the scope of this opinion, HHS now believes that the phrase "entitled to benefits under Part A" should also include patients enrolled in a Part C plan. HHS therefore contends that Part C patient days should be included in the Medicare fractions. Many hospitals disagree. They argue that Part C enrollees are *not* "entitled to benefits under Part A" and that Part C days therefore should *not* be included in Medicare fractions.

That difference in interpretation makes a huge difference in the real world. Part C enrollees tend to be wealthier than Part A enrollees. Including Part C days in Medicare fractions therefore tends to lead to lower reimbursement rates. Ultimately, hundreds of millions of dollars are at stake for the Government and the hospitals. *See Northeast Hospital Corp. v. Sebelius*, 657 F.3d 1, 5 (D.C. Cir. 2011).

Before 2004, HHS had *not* treated Part C enrollees as "entitled to benefits under Part A." *See id.* at 15. In 2004, however, HHS promulgated a rule announcing

that Part C enrollees *are* "entitled to benefits under Part A" and that HHS would therefore include Part C days in Medicare fractions. *See* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates, 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004). That 2004 rule would have applied HHS's changed interpretation prospectively to all Medicare fraction calculations from fiscal year 2005 onward. However, this Court vacated the 2004 rule on the grounds that it was not a logical outgrowth of the proposed rule and had therefore been improperly issued without notice and opportunity for comment. *See Allina Health Services v. Sebelius*, 746 F.3d 1102, 1107-09 (D.C. Cir. 2014). As a result, HHS can no longer rely on the 2004 interpretation.

In 2013, HHS promulgated a new rule again announcing that HHS would treat Part C enrollees as "entitled to benefits under Part A" and that HHS would therefore include Part C days in Medicare fractions. *See* 78 Fed. Reg. 50,496, 50,614 (Aug. 19, 2013). The 2013 rule is prospective only: It applies to Medicare fractions calculated for fiscal year 2014 and beyond. *Id.* at 50,619. It does not address the definition of "entitled to benefits under Part A" for any fiscal years before 2014. In sum, HHS has no promulgated rule governing the interpretation of "entitled to benefits under Part A" for the fiscal years before 2014.

B

In June 2014, HHS published the Medicare fractions to be used in calculating disproportionate share hospital adjustments for fiscal year 2012. At the top of the spreadsheet containing those fractions, HHS noted that it had included Part C days in the Medicare fractions.

The spreadsheet contained the 2012 Medicare fractions for all hospitals nationwide.

Plaintiffs in this case are hospitals that provide health care to low-income Medicare patients and that are therefore entitled to disproportionate share hospital adjustments. Those hospitals here challenge HHS's June 2014 decision to include Part C days in the 2012 Medicare fractions.

As required by statute, the hospitals first sought review by the Provider Reimbursement Review Board within HHS. But the hospitals believed that the Board did not have the authority to resolve the hospitals' challenges because the hospitals' challenges related to the validity of several HHS regulations. Under HHS's rules implementing the Medicare statute, the Board may not review challenges "either to the constitutionality of a provision of a statute, or to the substantive or procedural validity of a regulation." 42 C.F.R. § 405.1842(f)(1). The hospitals therefore sought expedited judicial review, which is available under the statute when the Board certifies that it does not have authority to resolve a provider's challenge. When the Board so certifies, the provider may bring suit in district court without proceeding through the full Board review process. *See* 42 U.S.C. § 1395*oo*(f)(1).

Here, the Board agreed with the hospitals that it did not have the authority to resolve the hospitals' challenge. That no-authority determination allowed the hospitals to promptly bring suit in District Court challenging HHS's decision to include Part C days in the Medicare fractions for fiscal year 2012.

In the District Court, HHS moved to dismiss the hospitals' case on the ground that the case was premature. HHS argued that the Board's no-authority determination was erroneous, and that the District Court therefore did not have authority to consider the challenges to the Medicare fractions until the Board ruled on that claim. The hospitals responded that the Board's no-authority determination was not reviewable by the District Court and that, in any event, the Board's no-authority determination was correct. The District Court agreed with HHS that the District Court could review the Board's no-authority determination. The District Court agreed with the hospitals, however, that the Board's no-authority determination was correct. The District Court therefore denied HHS's motion to dismiss.

Both sides then moved for summary judgment on the merits of the hospitals' challenges. The hospitals contended that HHS violated the Administrative Procedure Act and the Medicare Act by including Part C days in the fiscal year 2012 Medicare fractions without first providing the public with notice and opportunity for comment. They also argued that the calculations were arbitrary and capricious. HHS responded that its decision was procedurally and substantively proper.

The District Court granted summary judgment to HHS. First, the District Court held that the June 2014 decision to include Part C days in the 2012 Medicare fractions was an "interpretive rule" under the APA. As a result, the District Court concluded that HHS's publication of the fiscal year 2012 Medicare fractions was statutorily exempt from the APA's notice-and-comment requirements. Second, the District Court held that the Medicare Act incorporated the APA's notice-and-

comment exception for interpretive rules. The District Court therefore held that HHS had not violated the Medicare Act's procedural requirements. Third, the District Court held that HHS's decision to include Part C days in the 2012 Medicare fractions was not arbitrary and capricious.

The hospitals now appeal the District Court's grant of summary judgment to HHS. This Court reviews a district court's grant of summary judgment de novo. *See Southeast Alabama Medical Center v. Sebelius*, 572 F.3d 912, 916 (D.C. Cir. 2009).

II

HHS's Provider Reimbursement Review Board concluded that it lacked authority to decide this dispute. The Board therefore certified the case for expedited judicial review in the District Court. The District Court concluded that it had authority to decide the case. We must first consider whether the District Court correctly concluded that it had authority to decide the case now, or whether the dispute instead should have been decided first by HHS's Provider Reimbursement Review Board.

HHS argues that the dispute should have been decided first by the Board. The hospitals raise two alternative points in response. They contend that the District Court may not review the Board's no-authority determination. The hospitals also argue in the alternative that even if the District Court may review the Board's no-authority determination, the Board here was correct to conclude that it did not have authority to hear the hospitals' challenge. We agree with the hospitals on both alternative arguments.

To begin, the hospitals are correct that a district court may not review the Board's no-authority determination at HHS's request. The Medicare Act states that providers—and only providers—"*shall*" have "the right to obtain" expedited judicial review "*whenever* the *Board* determines . . . that it is without authority to decide" a particular question. 42 U.S.C. § 1395*oo*(f)(1) (emphasis added).[1] In other words, providers are guaranteed expedited judicial review when the Board makes a no-authority determination, as the Board did here. The statute conditions expedited judicial review in the district court on the existence of that no-authority determination, *not* on whether that determination is correct.

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[1] As relevant here, the statutory provision for expedited judicial review reads: "Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider of services as described in the following sentence) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. If a provider of services may obtain a hearing under subsection (a) of this section and has filed a request for such a hearing, such provider may file a request for a determination by the Board of its authority to decide the question of law or regulations relevant to the matters in controversy (accompanied by such documents and materials as the Board shall require for purposes of rendering such determination). The Board shall render such determination in writing within thirty days after the Board receives the request and such accompanying documents and materials, and the determination shall be considered a final decision and not subject to review by the Secretary. If the Board fails to render such determination within such period, the provider may bring a civil action (within sixty days of the end of such period) with respect to the matter in controversy contained in such request for a hearing." 42 U.S.C. § 1395*oo*(f)(1).

The statutory structure confirms that reading of the text. A provider may bring suit in the district court even when the Board fails to make a timely determination of its authority to decide a case. *See id.* ("If the Board fails to render such determination within such period, the provider may bring a civil action (within sixty days of the end of such period) with respect to the matter in controversy contained in such request for a hearing."). As the hospitals rightly point out, it would be "nonsensical if judicial review could be defeated by disagreement with the Board's no-authority decision, even though the Board's failure to make such a decision undisputedly confers federal court jurisdiction." Allina Reply Br. 5.

Put simply, Congress has allowed providers to seek immediate judicial review when the Board concludes that an extensive and time-consuming administrative process before the Board would likely be pointless. Requiring parties in district court to fully brief and re-litigate the Board's assessment of its own lack of authority—a question that may often be inextricably linked to the merits of a provider's challenge—runs entirely counter to that statutory scheme.[2]

In any event, even if we were wrong about that point, the Board here was correct in deciding that it did not have authority to resolve the hospitals' challenge. Under HHS regulations implementing the statute's expedited judicial review procedure, the Board "must grant" expedited judicial review if the legal question

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[2] We recognize that our decision here breaks with other courts of appeals that have concluded that the Board's no-authority determinations are reviewable. *See, e.g., Providence Yakima Medical Center v. Sebelius*, 611 F.3d 1181, 1187 n.7 (9th Cir. 2010).

raised "is a challenge either to the constitutionality of a provision of a statute, or to the substantive or procedural validity of a regulation." 42 C.F.R. § 405.1842(f)(1). The hospitals here pressed two arguments before the Board. Both arguments challenged the "substantive or procedural validity" of different regulations. *Id.* § 405.1842(f)(1)(ii). First, the hospitals argued that HHS erred when it chose to apply the formula from the vacated 2004 rule in calculating the 2012 fractions. The hospitals' first argument therefore raised the question of the 2004 rule's continuing legal validity. Second, the hospitals argued that HHS violated various procedural requirements by promulgating a new regulation without notice-and-comment rulemaking. That argument turned on whether the decision to include Part C days in the 2012 Medicare fractions constituted a new regulation, and if it did, whether that new regulation was procedurally valid. Both of the hospitals' arguments raise legal questions about the "substantive or procedural validity of a regulation." *Id.* The Board's no-authority determination was correct. The District Court correctly concluded that it had authority to decide the case now.

III

A

We turn therefore to the hospitals' claim that HHS violated the Medicare Act by failing to provide for notice and comment before including Part C days in the 2012 Medicare fractions. We agree with the hospitals that HHS unlawfully failed to provide for notice and comment.

The Medicare Act describes in fairly straightforward language when notice and comment is necessary. Paragraph (2) of Section 1395hh(a) provides:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

42 U.S.C. § 1395hh(a)(2). Paragraph (1), in turn, requires the HHS Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs" under the Medicare Act. *Id.* § 1395hh(a)(1). With a few exceptions not relevant here, "the Secretary shall provide for notice of the proposed regulation" to allow "for public comment thereon." *Id.* § 1395hh(b)(1).

In other words, as relevant here, the Medicare Act requires notice-and-comment rulemaking for any (1) "rule, requirement, or other statement of policy" that (2) "establishes or changes" (3) a "substantive legal standard" that (4) governs "payment for services." *Id.* § 1395hh(a)(2). All four requirements are readily met here.

First, HHS's inclusion of Part C days in the fiscal year 2012 Medicare fractions is, at the very least, a "requirement." Fiscal intermediaries are *commanded* to use HHS's Medicare fractions in calculating adjustment amounts. *See* 42 C.F.R. § 412.106(b)(2), (5).

Those fractions treat Part C enrollees as "entitled to benefits under Part A." The fiscal intermediaries are therefore *required* to include Part C days in their calculations as they determine reimbursement adjustments. In short, HHS promulgated a "requirement" when it announced that the 2012 Medicare fractions would include Part C days.

Second, HHS's inclusion of Part C days in the fiscal year 2012 Medicare fractions represents a change in HHS's standards. Before 2004, HHS's standard practice was to *exclude* Part C days from Medicare fractions. *See Northeast Hospital Corp. v. Sebelius*, 657 F.3d 1, 15 (D.C. Cir. 2011). HHS's 2004 rule attempted to change that standard so that the Medicare fractions would *include* Part C days. *Id.* at 14. But that rule was vacated. *See Allina Health Services v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014) (*Allina I*). Although HHS promulgated a new rule in 2013 that includes Part C days in Medicare fractions, that rule applies only prospectively to reimbursement adjustments for fiscal years 2014 and beyond.[3] As a result, the pre-2004 standard of excluding Part C days from Medicare fractions remains the baseline practice from which this Court must evaluate any decisions for 2012. The decision to include Part C days in the 2012 Medicare fractions is therefore a change from prior practice.

Third, HHS's inclusion of Part C days in the fiscal year 2012 Medicare fractions establishes a "substantive legal standard." "Substantive law" is law that "creates, defines, and regulates the rights, duties, and powers of

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[3] The 2013 rule is the subject of pending litigation in the District Court. We express no views on the merits of that case.

parties." BLACK'S LAW DICTIONARY (10th ed. 2014). A "substantive legal standard" at a minimum includes a standard that "creates, defines, and regulates the rights, duties, and powers of parties." That is precisely what HHS's 2012 Medicare fractions do. The fiscal intermediaries must use HHS's published Medicare fractions in determining how much the hospitals will be reimbursed. HHS's fractions therefore define the scope of hospitals' legal rights to payment for treating low-income patients.

Fourth, HHS's inclusion of Part C days in the fiscal year 2012 Medicare fractions governs "payment for services." The fractions are used to calculate the payment that providers will receive for providing healthcare services to low-income patients. The inclusion of Part C days means that the providers will now receive lower payments.

In sum, HHS's decision to include Part C days in the 2012 Medicare fractions is covered by the text of Section 1395hh(a)(2). The Medicare Act therefore required HHS to engage in notice-and-comment rulemaking before deciding to include Part C days in the 2012 Medicare fractions. Because HHS did not undertake notice-and-comment rulemaking, the 2012 Medicare fractions are procedurally invalid.

B

HHS's arguments to the contrary are not persuasive.

First, HHS argues that the fractions are not a "rule, requirement, or statement of policy" because the fractions apply only to the parties in this particular case for the year 2012. That argument is factually inaccurate. HHS published Medicare fractions for *every hospital in the country*. All of those fractions include Part C

days. Indeed, during oral argument, HHS forthrightly acknowledged that it would "generally" maintain a "consistent interpretation" for all hospitals for a given year, meaning that the policy applied to the hospitals in this case would apply to all hospitals nationwide. Tr. of Oral Arg. at 29:20-21. Moreover, as the hospitals point out, the 2012 Medicare fractions will be the basis not just for 2012 adjustments, but also for interim 2013 payments until HHS publishes the 2013 fractions. *See* 42 C.F.R. § 413.64(e). In other words, the decision to include Part C days in the 2012 Medicare fractions affects more hospitals than just the parties in this particular case for this particular year.

Second, HHS argues that the Medicare Act incorporates the APA's exceptions to notice-and-comment requirements. According to HHS, even if the decision to include Part C days in the fiscal year 2012 Medicare fractions is a rule, it is at most an "interpretive rule" for purposes of the APA. As a result, it is exempt from the APA's—and, by extension, the Medicare Act's —notice-and-comment requirements.

The problem with that argument is that the Medicare Act does not incorporate the APA's interpretive-rule exception to the notice-and-comment requirement. (Therefore, we need not decide whether HHS's decision to include Part C days in the 2012 Medicare fractions was in fact an interpretive rule.)

Unlike the APA, the text of the Medicare Act does not exempt interpretive rules from notice-and-comment rulemaking. On the contrary, the text expressly *requires* notice-and-comment rulemaking. The Medicare Act states: "*No* rule, requirement, or other statement of policy . . . shall take effect *unless* it is promulgated"

through notice-and-comment rulemaking. 42 U.S.C. § 1395hh(a)(2) (emphasis added); *id.* § 1395hh(b)(1). The provision does not include an exception for interpretive rules. By contrast, the APA requires notice and comment only for "proposed rule making" and exempts "interpretative rules, general statements of policy, [and] rules of agency organization, procedure, or practice" from notice-and-comment requirements. 5 U.S.C. § 553(b). We must respect Congress's use of different language and its establishment of different notice-and-comment requirements in the Medicare Act and the APA. *Cf.* WILLIAM N. ESKRIDGE JR., INTERPRETING LAW: A PRIMER ON HOW TO READ STATUTES AND THE CONSTITUTION 109-10 (2016) ("Where a statute repeatedly uses one term or phrase, one expects that a materially different phraseology demands a different reading."); ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 170 (2012) ("[A] material variation in terms suggests a variation in meaning.").

Moreover, Congress knew how to incorporate the APA's notice-and-comment exceptions into the Medicare Act when it wanted to. After all, the Medicare Act expressly incorporates other APA notice-and-comment exceptions. Specifically, the Medicare Act incorporates the APA's "good cause" exception. *See* 42 U.S.C. § 1395hh(b)(2) (Notice-and-comment rulemaking requirement "shall not apply where— . . . subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection."). But in the Medicare Act, Congress did not incorporate the APA's interpretive-rule exception to notice-and-comment requirements.

We recognize that we are breaking with several other courts of appeals by holding that the Medicare Act does not incorporate all of the APA's exceptions to the notice-and-comment requirement. *See, e.g., Via Christi Regional Medical Center, Inc. v. Leavitt*, 509 F.3d 1259, 1271 n.11 (10th Cir. 2007); *Baptist Health v. Thompson*, 458 F.3d 768, 776 n.9 (8th Cir. 2006); *Omni Manor Nursing Home v. Thompson*, 151 Fed. App'x 427, 431 (6th Cir. 2005); *Warder v. Shalala*, 149 F.3d 73, 79 n.4 (1st Cir. 1998).[4] But we respectfully disagree with those opinions. As discussed, we conclude that the Medicare Act does not incorporate the APA's interpretive-rule exception to the notice-and-comment requirement.

C

Finally, even if HHS were correct that the Medicare Act somehow incorporated the APA's notice-and-comment exception for interpretive rules, HHS would still not prevail here. That is because another provision of the Medicare Act, Section 1395hh(a)(4), expressly required notice and comment in this case. Section 1395hh(a)(4) reads in full:

> If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect

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[4] As HHS points out, this Court's prior decision in *Monmouth Medical Center v. Thompson*, 257 F.3d 807, 814 n.2 (D.C. Cir. 2001), noted the question of whether the Medicare Act incorporates the APA's interpretive-rule exception. But as HHS recognizes, *Monmouth* did not "expressly decide the question" raised here. HHS Br. 44.

> until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

42 U.S.C. § 1395hh(a)(4). In other words, if a regulation includes a "provision that is not a logical outgrowth of a previously published notice of proposed rulemaking," that provision may not become legally operative until it has gone through notice-and-comment rulemaking. *Id.*

Section 1395hh(a)(4) applies with full force here. This Court vacated HHS's 2004 rule treating Part C enrollees as "entitled to benefits under Part A" because the 2004 rule "was not a logical outgrowth of the proposed rule." *Allina I*, 746 F.3d at 1109. HHS therefore had to provide a "further opportunity for public comment and a publication of the provision again as a final regulation" before HHS could re-impose the rule. 42 U.S.C. § 1395hh(a)(4). HHS did not do so. And HHS could not circumvent this requirement by claiming that it was acting by way of adjudication rather than rulemaking. The statutory text says that the vacated rule may not "take effect" at all until there has been notice and comment.

* * *

Because we conclude that HHS has failed to provide notice and comment as required by the Medicare Act, we need not consider whether HHS's decision was arbitrary and capricious. We reverse the judgment of the District Court and remand for proceedings consistent with this opinion.

So ordered.

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 14-1415 (GK)

ALLINA HEALTH SERVICES, ET AL., PLAINTIFFS

v.

SYLVIA M. BURWELL, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEFENDANT

[Filed: Aug. 17, 2016]

MEMORANDUM OPINION

Plaintiffs Allina Health Services, et al. ("Plaintiffs") are nine hospitals that bring this action against Sylvia M. Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services ("Secretary" or "Defendant"). They challenge the calculation of certain disproportionate share hospital payments as procedurally and substantively invalid.

This matter is before the Court on the Plaintiff's Motion for Summary Judgment [Dkt. No. 8] and Defendant's Cross-Motion for Summary Judgment [Dkt. No. 28]. Upon consideration of the Motions, Oppositions, Replies, the entire record herein, and for the reasons set forth below, Plaintiffs' Motion shall be **denied** and Defendant's Motion shall be **granted.**

I. Background

A. The Medicare DSH Payment System

The Medicare program was established in 1965 and provides health care coverage for persons age 65 and older, disabled persons, and persons with end stage renal disease who meet certain eligibility requirements. See 42 U.S.C. § 426, 426a. The Secretary administers the program through the Centers for Medicare & Medicaid Services (CMS), an agency with the United States Department of Health and Human Services. Def.'s Mot. at 4.

Medicare pays benefits through different plans, three of which are relevant here. "Plan A covers medical services furnished by hospitals and other institutional care providers." Ne. Hosp. Corp. v. Sebelius, 657 F.3d 1, 2 (D.C. Cir. 2011); 42 U.S.C. §§ 1395c to 1395i-5. "Part B is an optional supplemental insurance program that pays for medical items and services not covered by Part A, including outpatient physician services, clinical laboratory tests, and durable medical equipment." Ne. Hosp., 657 F.3d at 2; 42 U.S.C. §§ 1395j to 1395w-4. "Part C governs the 'Medicare + Choice' (M+C) program, which gives Medicare beneficiaries an alternative to the traditional Part A fee-for-service system," allowing enrollment in a managed care plan. Ne. Hosp., 657 F.3d at 2; see 42 U.S.C. §§ 1395w-21 to 1395w-29. The Secretary pays the health care provider directly under Parts A and B, but pays the managed-care plan under Part C, which in turn pays the provider.

Hospitals that serve a significantly disproportionate share of low-income patients without private health insurance are paid "additional monies [by Medicare], on

top of Medicare's normal fees-for-service, to help cover the costs associated with the care of the very poor." Allina Health Servs. v. Sebelius, 904 F. Supp. 2d 75, 77 (D.D.C. 2012) ("Allina I"); see also 42 U.S.C. § 1395ww(d)(5)(F); 42 C.F.R. § 412.106.

The disproportionate share hospital ("DSH") adjustment is based on a "disproportionate patient percentage" for each hospital, which is determined by a complicated statutory formula. See 42 U.S.C. §§ 1395ww(d)(5)(F)(iv) and (vii)-(xiii); 42 C.F.R. § 412.106(d). The disproportionate patient percentage is the sum of two fractions, 42 U.S.C. § 1395ww(d)(5)(F)(vi), which are commonly known as the "Medicaid fraction" and the "Medicare fraction" (sometimes also referred to as the "SSI fraction").

The Medicare fraction is defined as:

> the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of [Title XVIII] and were entitled to supplemental security income benefits (excluding any State supplementation) under [Title] XVI of this chapter, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of [Title XVIII] . . .

42 U.S.C. § 1395ww(d)(5)(F)(vi)(I) (emphasis added). In layman's terms, the top of the Medicare fraction is based on the number of a hospital's patient days for individuals entitled to both Medicare Part A and SSI benefits, and the bottom of the fraction is based on the

number of patient days for all patients under Part A. As discussed later, the phrase "entitled to benefits under part A" is key to the present dispute.

The Medicaid fraction is defined as:

> the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State [Medicaid] plan . . . but who were not entitled to benefits under [Medicare] Part A . . . and the denominator of which is the total number of the hospital's patient days for such period.

Id. § 1395ww(d)(5)(F)(vi)(II). In layman's terms, the top of the Medicaid fraction is based on the number of a hospital's patient days for individuals who are eligible for Medicaid, but who are not entitled to benefits under Medicare Part A, and the bottom is the total number of all patient days for the hospital. For a visual representation of the fractions, see Ne. Hosp., 657 F.3d 1, 3.

M+C (also referred to as Part C) was established by Congress in 1997 as part of the Balanced Budget Act of 1997 (BBA), Pub. L. No. 105-33 (1997). In order to enroll in M+C, an individual must be "entitled to benefits under part A . . . and enrolled under part B." 42 U.S.C. § 1395w-21(a)(3)(A). After M+C was implemented, "the Secretary routinely excluded M+C [inpatient hospital] days from the Medicare fraction" from 1999 to 2004. Ne. Hosp., 657 F.3d at 15. That is, M+C patients were not counted in the numerator of the Medicare fraction as part of the patients "entitled to benefits under Part A . . . and entitled to [SSI] benefits." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I). It was

not until 2007 that the Secretary began to collect the data needed to include M+C days in the Medicare/SSI fraction. Id.; see Change Request 5647, CMS Pub. 100-04, Transmittal No. 1331 (July 20, 2007).

Central to this case is whether, once enrolled in Part C, enrollees continue to be entitled to benefits under Part A. If the agency considers enrollees to be entitled to benefits under Part A, then they should be included in the Medicare fraction. If they are no longer entitled to benefits under Part A, because they are receiving benefits under Part C, then they should be excluded from the Medicare fraction. The financial impact on the hospitals of this seemingly minor detail is in the hundreds of millions of dollars. See Allina Health Servs. v. Sebelius, 746 F.3d 1102, 1105 (D.C. Cir. 2014) ("Allina I Appeal").

B. Factual Background

In Allina I, a group of hospitals, including the Plaintiffs in the present case, challenged a 2004 rulemaking by the Secretary ("2004 Final Rule"). See 904 F. Supp. 2d at 77. The 2004 rulemaking adopted a policy whereby Part C patients were to be considered as "entitled to benefits under part A," and therefore counted in the numerator of the Medicare fraction. In November 2012, the Court (Collyer, J.) granted summary judgment for the plaintiffs, finding that the 2004 Final Rule was not a logical outgrowth of the proposed rule and therefore violated the procedural requirements of the Administrative Procedure Act ("APA"). See Allina I, 904 F. Supp. 2d at 89-90.

On appeal, our Court of Appeals affirmed the part of the Allina I Court's decision vacating the 2004 Final

Rule. But, the Court of Appeals held that the Allina I Court erred when it directed the Secretary to calculate the DSH payments in a particular manner, rather than simply remanding. See Allina I Appeal, 746 F.3d 1102, 1111 (D.C. Cir. 2014). On remand, the Secretary addressed the issue of the appropriate DSH calculation methodology through an adjudication. The Administrator determined that, prior to 2004, the regulation did not specify where the Part C enrollees should be counted in the DSH percentage. Allina I, Adm'r Dec. at 26 (Dec. 2, 2015) [Dkt. 28-2]. The Administrator further concluded that the better statutory interpretation is that Part C enrollees are "entitled to benefits under Part A" within the meaning of the DSH provisions, and therefore should be included in the Medicare fraction. Id. at 35-45.

C. Procedural Background

Shortly after our Court of Appeals' decision in Allina I, the Secretary published calculations for federal fiscal year 2012 DSH payments ("2012 DSH Calculations").[1] See 2012 Part A/SSI Fraction Data File, available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY-2012-SSI-Ratios-for-web-posting.zip. Plaintiffs allege that the 2012 DSH Calculations are based on the 2004 Final Rule that was vacated. They also allege that the

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[1] The present action is not considered part of the Allina I remand, because it concerns a later year. In 2013, the HHS adopted a legislative rule that interprets the statute to require Part C days in the Medicare fraction. 78 Fed. Reg. 50,496, 50,614 (Aug. 19, 2013) ("2013 Rulemaking"). The legislative rule only has prospective application, and therefore does not apply to this case or the Allina I remand. Id. at 50,620.

2012 DSH Calculations are procedurally invalid and arbitrary and capricious. Compl. ¶¶ 46-52. Plaintiffs timely appealed the 2012 DSH Calculations to the Provider Reimbursement Review Board ("PRRB"), see Compl. ¶¶ 36-39, and requested that the PRRB grant expedited judicial review. Id. ¶ 41.

The PRRB is an independent administrative tribunal that resolves disputes regarding hospital reimbursement determinations by Medicare contractors or the Centers for Medicare & Medicaid Services ("CMS"). See 42 U.S.C. § 1395oo(a). The PRRB may resolve certain payment disputes without following low-level policy guidance, see 42 C.F.R. § 405.1867; however, it is bound by agency regulation and rulings, id., and cannot decide "question[s] of law or regulations." 42 U.S.C. § 1395oo(f)(1). Section 1395oo(f) gives providers "the right to obtain judicial review of any action . . . which involves a question of law or regulations . . . whenever the [PRRB] determines . . . that it is without the authority to decide the question." Id.

By letter dated August 13, 2014, the PRRB granted Plaintiffs' request for expedited judicial review, finding that "it is without the authority to decide the legal question of whether the regulation regarding the [2012 DSH Calculations] is valid and whether the Secretary's actions subsequent to the decision in Allina [I] are legal." Letter from the Provider Reimbursement Review Board to Stephanie Webster 6 (Aug. 13, 2014) [Dkt. No. 14-1] ("PRRB Decision").

On August 19, 2014, Plaintiffs filed their Complaint, pursuant to the PRRB's grant of expedited judicial review [Dkt. No. 1]. Plaintiffs filed a Notice of Related Case on the same day [Dkt. No. 2]. Judge Collyer

granted Defendant's objection to the related case designation on May 18, 2015, and the case was randomly reassigned to this Court. Minute Order dated May 18, 2015; Case Assignment [Dkt. No. 20].

On October 27, 2014, Defendant filed her Motion to Dismiss for Lack of Jurisdiction or in the Alternative for Voluntary Remand [Dkt. No. 15], arguing that the PRRB improvidently granted expedited judicial review, or in the alternative, for voluntary remand to allow the PRRB to adjudicate Plaintiffs' claims without consideration of the 2004 Final Rule. Motion to Dismiss at 2. The Court denied Defendant's Motion to Dismiss on October 29, 2015 [Dkt. No. 21].

Plaintiffs filed their present Motion for Summary Judgment on September 29, 2014 [Dkt. No. 8], prior to Defendant's response to the Complaint. On October 17, 2014, the Court (Collyer, J.) granted Defendant's Motion to hold in abeyance the Motion for Summary Judgment until the Motion to Dismiss was filed and decided. See October 17, 2014 Minute Order. After this Court denied Defendant's Motion to Dismiss, Defendant filed her Answer on November 12, 2015 [Dkt. No. 24], and her Cross-Motion for Summary Judgment ("Def.'s Mot.") on December 15, 2015 [Dkt. No. 29]. Plaintiffs filed their Opposition ("Opp'n") on January 14, 2016 [Dkt. No. 30] and Defendant filed her Reply ("Reply") on February 4, 2016 [Dkt. No. 33]. On February 12, 2016, Plaintiffs filed a Motion for Leave to File a Sur-Reply [Dkt. No. 34], which Defendant opposed [Dkt. No. 35], and the Court denied on February 18, 2016 [Dkt. No. 36].

II. Legal Standard

A. Motion for Summary Judgment

Summary judgment will be granted when there is no genuine issue as to any material fact. See Fed. R. Civ. P. 56(a). Because this case involves a challenge to a final administrative decision, the Court's review on summary judgment is limited to the administrative record. Holy Land Found. for Relief & Dev. v. Ashcroft, 333 F.3d 156, 160 (D.C. Cir. 2003) (citing Camp v. Pitts, 411 U.S. 138, 142 (1973)); Fund for Animals v. Babbitt, 903 F. Supp. 96, 105 (D.D.C. 1995) ("Summary judgment is an appropriate procedure for resolving a challenge to a federal agency's administrative decision when review is based upon the administrative record").

"Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." Sierra Club v. Mainella, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) (citing Richards v. INS, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977)). In reviewing agency action, the district court "sits as an appellate tribunal, not as a court authorized to determine in a trial-type proceeding whether the Secretary's [action] was factually flawed." Marshall Cnty. Health Care Auth. v. Shalala, 988 F.2d 1221, 1225 (D.C. Cir. 1993).

B. Requirements of the APA and Medicare Act

Under the APA and the Medicare Act, legislative rules—rules that have the "force and effect of law," Chrysler Corp. v. Brown, 441 U.S. 281, 302-303, (1979)) —are issued through notice-and-comment rulemaking, in which the Secretary must provide the public with ad-

equate notice of a proposed rule and an opportunity to comment thereon. See 5 U.S.C. § 553(b)-(c) (APA); 42 U.S.C. § 1395hh(b)(1) (Medicare) ("[B]efore issuing in final form any regulation . . . the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon."). "Notice requirements are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." Int'l Union, UMWA v. MSHA, 407 F.3d 1250, 1259 (D.C. Cir. 2005). The 2012 DSH Calculations were not issued through notice and comment rulemaking, although Plaintiffs argue that they should have been. Pls.' Mot. at 9; Pls.' Reply at 10.

Not all rules require notice-and-comment prior to issuance. Section 4(b)(A) of the APA provides that, unless another statute states otherwise, the notice-and-comment requirement "does not apply" to "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). "[T]he critical feature of interpretive rules is that they are 'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'" Perez v. Mortgage Bankers Ass'n, 135 S. Ct. 1199, 1204 (2015) (quoting Shalala v. Guernsey Memorial Hospital, 514 U.S. 87, 99 (1995)).

The D.C. Circuit had long held that, even though notice and comment was not necessary for new interpretive rules issued by an agency, notice and comment

was nonetheless required when an agency changed its prior interpretation. Paralyzed Veterans of Am. v. D.C. Arena L.P., 117 F.3d 579 (1997). Overturning Paralyzed Veterans and its subsequent line of cases, the Supreme Court recently held that an agency need not use notice-and-comment procedures "when it wishes to issue a new interpretation of a regulation that deviates significantly from one the agency has previously adopted." Perez, 135 S. Ct. 1199 at 1203.

The APA also allows a reviewing court to set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); Tourus Records, Inc. v. DEA, 259 F.3d 731, 736 (D.C. Cir. 2001). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). The court must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." S. Co. Servs., Inc. v. FCC, 313 F.3d 574, 579-80 (D.C. Cir. 2002); see also United States v. Paddack, 825 F.2d 504, 514 (D.C. Cir. 1987) .

An agency satisfies the arbitrary and capricious standard if it "examine[s] the relevant data and articulate[s] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" Motor Vehicle Mfrs. Ass'n, 463 U.S. at 43 (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)); Lichoulas v. FERC, 606 F.3d 769, 775 (D.C. Cir. 2010). However, courts "do not defer to the agency's conclusory or unsupported suppositions."

McDonnell Douglas Corp. v. U.S. Dep' t of the Air Force, 375 F.3d 1182, 1186-87 (D.C. Cir. 2004).

III. Analysis

A. The Evidence Is Not Convincing that CMS Calculated the 2012 DSH Fractions Based on the Vacated 2004 Final Rule.

Plaintiffs argue that the Secretary improperly relied on the vacated 2004 Final Rule to formulate the 2012 DSH Calculations, Pls.' Mot. at 6-7, while Defendant counters that the 2012 DSH Calculations were reached by CMS in reliance on the language of the disproportionate patient percentage statute itself. Def.'s Mot. at 9.

What is central to this dispute is the parties' disagreement as to the impact of the vacatur of the 2004 Final Rule. Defendant argues that "the agency was faced with an ambiguous direction from Congress" and that the pre-2004 version of the applicable regulation did not specify where Part C days should be counted. Id. at 10. Plaintiffs on the other hand argue that pre-2004, the agency had a policy of excluding Part C days from the Medicare fraction. Pls.' Reply at 4. In the alternative, Plaintiffs argue that even if there was not a policy or regulation excluding Part C days from the Medicare fraction, the agency had a prior practice of excluding the Part C days, which was reinstated after the vacatur of the 2004 Final Rule. Id. (citing Croplife Am. v. EPA, 329 F.3d 876, 880, 884-85 (D.C. Cir. 2003).

Defendant contends that there is no evidence to directly suggest that the 2012 DSH Calculations were based on the vacated 2004 Final Rule, rather than on CMS's interpretation of the statute. Def.'s Mot. at 10. Conversely, Plaintiff argues that there is no evidence

to suggest that the Secretary did not rely on the vacated rule. The Secretary states that CMS "inevitably had to employ one of two possible interpretations of the statutory language," and the one it chose for the 2012 DSH Calculations reflected CMS's best understanding of the statutory language itself. Def.'s Mot. at 10 (citing Declaration of Ing Jye Cheng ("Cheng Decl.") ¶¶ 7, 8 [Dkt. No. 29-3]). Acknowledging that the 2004 Final Rule is no longer in effect, the Secretary cites to the Allina I Administrator decision as evidence that the agency is no longer relying on the vacated 2004 Final Rule. Id.

Our Court of Appeals, in remanding Allina I to allow the agency to consider the interpretive issue anew, made it clear that it was possible the agency could and might adopt the same interpretation contained in the 2004 Final Rule. Allina I Appeal, 746 F.3d at 1111. Consequently, it follows that the fact that the agency did adopt the same interpretation as the 2004 Final Rule is not—in and of itself—indicative that the 2004 Final Rule was relied upon.

While it may have been far better if the agency had provided an explanation of its interpretation of the DSH statute along with the 2012 DSH Calculations, particularly in light of the vacatur of the 2004 Final Rule, there is no con incing evidence that Defendant actually relied on the vacated rule in promulgating the 2012 DSH Calculations. Indeed, as the Court later concludes, the Secretary appropriately relied on and interpreted the underlying DSH statute to calculate the 2012 DSH Calculations.

B. Notice and Comment Rulemaking Was Not Required

i. The APA

The parties agree that the Secretary did not undertake notice and comment rulemaking to implement a rule including Part C days in the Medicare fraction that is applicable to the 2012 DSH Calculations. The issue is whether the Secretary should have.

The APA requires notice and comment when agencies implement new legislative rules. 5 U.S.C. § 553(b). Plaintiffs argue that the 2012 DSH Calculations were not a one-time decision, but instead were the beginning of an ongoing pattern and therefore should be considered a legislative rule. Pls.' Reply at 23. Plaintiffs reason that the 2012 DSH Calculations "'reflect' a universal policy of treating part C days as part A days for all hospitals," because the agency has continued to include Part C days in the Medicare fraction in all future actions. Id. Therefore, Plaintiffs continue, the 2012 DSH Calculations constitute "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy," and are therefore a "rule" for purposes of the APA Id. (citing 5 U.S.C. § 551(4)).

Defendant takes issue with the characterization of the 2012 DSH Calculations as involving a rule at all. The 2012 DSH Calculations are comprised solely of a spreadsheet of percentages,[2] which Defendant charac-

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[2] The 2012 DSH Calculations are available at http://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/AcuteInpatientPPS/Downloads/FY-2012-SSI-Ratios-for-web-posting.zip.

terizes as "preliminary, provider-specific determinations calculated on the basis of services that had already been rendered." In other words, Defendant argues that the 2012 DSH Calculations are more appropriately viewed as a step in an adjudication rather than as a rule. Def.'s Mot. at 12.

However, Defendant acknowledges that the fractions "do reflect an interpretation of the statute that Part C days are included in the Medicare fraction." Id. (emphasis in original). The 2012 DSH Calculations were not merely a step in an adjudication, but reflect a decision by the agency to include Part C days in the Medicare fraction. Thus, the 2012 DSH Calculations are not appropriately viewed as a step in an adjudication but rather as a rule.

The Court must now determine whether the agency was announcing a new legislative rule or simply interpreting the statute and announcing an interpretive rule. A "legislative rule," is a rule intended to have and does have the force of law. "A valid legislative rule is binding upon all persons, and on the courts, to the same extent as a congressional statute. When Congress delegates rulemaking authority to an agency, and the agency adopts legislative rules, the agency stands in the place of Congress and makes law. An 'interpretative' rule, by contrast, does not contain new substance of its own but merely expresses the agency's understanding of a congressional statute." Nat'l Latino Media Coal. v. F.C.C., 816 F.2d 785, 787-88 (D.C. Cir. 1987).

Factors to consider when determining whether a rule has a "legal effect" include "asking 1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency

action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. If the answer to any of these questions is affirmative, we have a legislative, not an interpretive rule." Am. Min. Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993).

The answer to all of the above questions is "no." As our Court of Appeals has previously recognized, the DSH statute is ambiguous and could be interpreted to include or exclude Part C days. Ne. Hosp., 657 F.3d at 5-6. The fact that the statute could be interpreted to include Part C days indicates that there is an adequate legislative basis for the agency's decision. The rule of including Part C days in the Medicare fraction, as applied to the 2012 DSH Calculations, was not published in the Code of Federal Regulations, nor did the agency explicitly invoke its legislative authority. Lastly, the rule does not amend a prior legislative rule.[3]

For these reasons, the Court concludes that the agency did not issue a legislative rule when it issued the 2012 DSH Calculations, and therefore APA notice and comment were not necessary. Instead, the 2012 DSH Calculations constitute the agency's interpreta-

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[3] Plaintiffs argue that the agency had a prior policy, rather than simply a practice, of excluding Part C days. See Pls.' Opp'n at 7-8. The facts do not support a finding of a policy, rather than simply a practice. Even if the agency did have a prior policy, it would not have been a legislative policy requiring notice and comment to change it.

tion of the disproportionate patient percentage statute. The statute itself provides an "adequate legislative basis" for including Part C days in the Medicare fraction, and therefore the rule underlying the 2012 DSH Calculations is interpretive. See Am. Min. Cong., 995 F.2d at 1112.

Plaintiffs argue that, because the agency previously promulgated the same interpretation through notice and comment rulemaking in the 2004 Final Rule and the 2013 Rulemaking, it should continue to do so for the 2012 DSH Calculations. Pls.' Reply at 28-30. However, there is no requirement that the agency continue to do so. For example, an agency may choose to invoke its general legislating authority out of an abundance of caution. Am. Min. Cong., 995 F.2d at 1110-11. Therefore, the agency's prior invocation of its general legislating authority (here, the 2004 Final Rule), is not per se evidence that it needed to do so and does not negate the Court's finding that the agency's action was interpretive.

ii. The Medicare Statute

The Medicare statute also requires notice and comment prior to the Secretary issuing final regulations. See 42 U.S.C. § 1395hh(b). Plaintiffs argue that the Medicare statute requires "rulemaking for a more expansive set of agency pronouncements than the APA." Pls.' Reply at 11. Plaintiffs cite to no cases in support of their argument and the Court finds their statutory interpretation arguments unpersuasive. Pls. Reply at 11-13.

Our Court of Appeals has not decided whether the Medicare statute "creates a more stringent obligation [than the APA] or whether it somehow changes the

dividing line between legislative and interpretive rules." Monmouth Med. Ctr. v. Thompson, 257 F.3d 807, 814 (D.C. Cir. 2001). However, the Court of Appeals did note that, because the Medicare statute was adopted after the APA, it was fair to infer that "§ 1385hh(c)'s reference to, 'interpretive rules' without any further definition adopted an exemption [to notice and comment requirements] at least similar in scope to that of the APA." Id. (internal citation omitted). Other circuit courts have similarly concluded, though without thorough analysis, that the standards imposed by the APA and Medicare are not materially different. See Baptist Health v. Thompson, 458 F.3d 768, 776 (8th Cir. 2006) (42 U.S.C. § 1395hh(a)(2) "imposes no standards greater than those established by the APA."); Erringer v. Thompson, 371 F.3d 625, 633 (9th Cir. 2004) (declining to determine whether the Medicare Act "draws the line between substantive and interpretive rules in a different place than the APA"); Warder v. Shalala, 149 F.3d 73, 79 n.4 (1st Cir. 1998) ("the [Medicare statute's] language, drafted after the APA's, can fairly be read to duplicate the APA on this score.").

Even if the Medicare statute was more demanding, the Secretary's interpretation of the DSH statute is not a "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard" such that notice and comment would be required. See 42 U.S.C. § 1395hh(a)(2). As discussed previously, in the absence of any regulation or rule, there is an "adequate legislative basis" for the Secretary's interpretation and application of the statute. American Mining Congress, 995 F.2d at 1112. The agency's interpretation of the statute does not require rulemaking under the Medicare statute.

iii. Rulemaking Through Adjudication

Defendant argues that notice and comment rulemaking is not necessary because it is "well-established that an agency may employ a new interpretation in the course of an individual adjudication." Def.'s Mot. at 12 (citing Shalala v. Guernsey Mem'l Hosp., 514 U.S. 87, 97 (1995) ("The APA does not require that all the specific applications of a rule evolve by further, more precise rules rather than by adjudication. The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate" (internal citations omitted))); see also Clark-Cowlitz Joint Operating Agency v. FERC, 826 F.2d 1074, 1081 (D.C. Cir. 1987) (en banc) ("[W]hen as an incident of adjudicatory function an agency interprets a statute, it may apply that new interpretation in the proceeding before it."). Defendant also points out that the decision whether to make new policy through adjudication or rulemaking is generally within the agency's discretion. Id. at 13 (citing NLRB v. Bell Aerospace Co. Div. of Textron, 416 U.S. 267, 291-94 (1974)). Given this, authority, Defendant concludes that it was "well within CMS's discretion to employ the interpretation it did in the course of calculating the 2012 [DHS Calculations]." Id.

Whether or not Defendant can issue new interpretations through adjudication is not relevant to this case, because the agency did not engage in an adjudication to reach the 2012 DSH Calculations. Defendant attempts to rely on a 2007 adjudication as authority for its policy in the 2012 DSH Calculations, but this reliance is misplaced. Def.'s Mot. at 14 (citing St. Joseph's Hosp. v. Blue Cross/Blue Shield Ass'n, 2007 WL 4861952 at *5

(Nov. 13, 2007)). St. Joseph's was not a forward looking policy and was limited to fiscal years 1998, 1999, and 2000. St. Joseph's Hosp., 2007 WL 4861952 at *1. In addition, the PRRB reached its decision, later affirmed by the Administrator, with reference to the now vacated 2004 Final Rule, which calls into question any prospective validity St. Joseph's may have had. See PRRB Decision (Aug. 27, 2004), available at https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Downloads/2007d68.pdf

Therefore, an agency's ability to issue new interpretive rules through adjudication does not help Defendant's case here.

iv. Prior Definitive Interpretation

As discussed previously, in Perez, the Supreme Court overruled the Court of Appeals' Paralyzed Veterans doctrine, which had created a judge-made procedural requirement that an agency use notice-and-comment rulemaking whenever it changed a rule interpreting a statute, even though such notice-and-comment would not have been required when interpreting the statute in the first instance. See supra, 12. Plaintiffs acknowledge that changes to an interpretive rule are no longer subject to notice and comment under the APA, and have withdrawn that argument. See Pls.' Reply at 16 n.10.

Even so, Plaintiffs contend that a "policy that 'works substantive changes' or makes 'major substantive legal additions' to existing regulations requires notice and comment.' Pls.' Reply at 19 (quoting U.S. Telecom Ass'n v. FCC, 400 F.3d 29, 34-35 (D.C. Cir. 2005)). Plaintiffs argue that the 2012 DSH Calculations effected

a substantive change and therefore should have undergone notice and comment procedures. Id. at 19-20. This argument misunderstands U.S. Telecom, which does not stand for the proposition that there are certain instances where interpretive rules require notice and comment. Rather, it held that new rules that affect substantive changes or amend prior legislative rules may more appropriately be considered legislative rules rather than interpretive rules. U.S. Telecom Ass'n, 400 F.3d at 34-35. The Court has already determined that the policy that was effectively announced in the 2012 DSH Calculations was an interpretive one, not legislative. See supra 19. Because the agency's action was interpretive, notice and comment was not required.

C. The Decision to Include Part C Days Is Not Arbitrary and Capricious

Plaintiffs argue that the Secretary's decision to include Part C days in the Medicare fraction was arbitrary and capricious. See Pls.' Reply at 32. Plaintiffs' contention has two prongs: first, that the agency's "no-process determination for all hospitals" is arbitrary and capricious, and second, that the agency's decision is impermissibly inconsistent with the underlying statutory scheme. Id. at 32-33.

As to the first, Plaintiffs contend that the Secretary's policy determination is arbitrary and capricious because the agency has not "articulated any rationale for its choice." Pls. Reply at 33 (quoting Republican Nat'l Comm. v. FEC, 76 F.3d 400, 407 (D.C. Cir. 1996). The scope of review under the arbitrary and capricious standard is a narrow one. The Court is not to substitute its own judgment, but the "agency must examine

the relevant data and articulate a satisfactory explanation for its action." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42-43 (1983). The court may not supply reasoning that the agency itself has not provided. Id. at 43. However, the court will "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." Id. (quoting Bowman Transp. Inc. v. Arkansas-Best Freight Sys., 419 U.S. 281, 286 (1974)).

Defendant blames the absence of a contemporaneous explanation for its decision to include Part C days in the Medicare fraction in the 2012 DSH Calculations on the unique posture of the case. Def.'s Mot. at 25-26. Defendant explains that the agency expected further administrative proceedings in connection with the challenge and regarded the decision as non-final. Id. at 26. Even if the Defendant expected "further administrative development" before the PRRB and Administrator, id., it is not clear why the agency would not provide any contemporaneous explanation with the issuance of the 2012 DSH Calculations. The agency also contends it was a one-time interpretive decision and as such, Plaintiffs are not entitled to expect an explanation of the sort that CMS would provide for a final prospective rule. Id.

Despite the lack of explanation, Defendant argues that the interpretative choice "can be readily sustained on the basis of the explanation set forth in the Administrator's decision in the Allina I remand." Id. at 27. Defendant concedes that the Court's review is ordinarily limited to the contemporaneous record developed by the agency, but argues that an exception is warranted. Id. (citing SEC v. Chenery Corp., 318 U.S. 80 (1943);

Glob. Crossing Telecomms., Inc. v. Metrophones Telecomms., Inc., 550 U.S. 45, 63-64 (2007)).

Chenery stands for the proposition that "an agency's decision must reflect the reasons for its action, and that subsequent rationalizations cannot be substituted on appeal for contemporaneous reasoned decisionmaking." Pub. Serv. Co. of Indiana v. I.C.C., 749 F.2d 753, 759 (D.C. Cir. 1984) (citing Chenery, 318 U.S. at 92-95). But Chenery is not absolute. In Global Crossing, the Supreme Court found that the FCC's initial opinion did not explain its determination, but nevertheless upheld the determination, finding that the "context and cross-referenced opinions ma[d]e the FCC's rationale obvious." Glob. Crossing Telecomms., 550 U.S. at 63 (internal citations omitted).

The Secretary argues that the instant case is akin to Global Crossing in that the Administrator's Allina I decision provides evidence of the agency's reasoning and therefore the agency's rationale is adequately explained. Def.'s Reply at 27. However, the Administrator's Decision, which was issued in December 2015, was not yet issued at the time of the 2012 DSH Calculations, which were issued in 2014. Although the 2013 Rulemaking had been issued, it is prospective only. See 78 Fed. Reg. 50,496, 50,614 (Aug. 19, 2013). In addition, unlike Global Crossing, the 2012 DSH Calculations do not include any cross-references to opinions or documents that shed light on the agency's rationale.

Defendant argues that it "'would be a waste of time to review only' the contemporaneous agency record to the 2012 DSH Calculations when the agency has subsequently issued in 2015 a 'better considered' decision upon which review may be based." Def.'s Mot. at 28

(quoting Pub. Serv. Co., 749 F.2d at 760). Public Service is easily distinguished from the case at hand, as it involved a clarifying opinion. The Commission had provided a first opinion, but then at the request of the petitioners to reopen the decision, reconsidered the record and issued a second clarifying opinion. The issue there was whether the second opinion could be considered. Such is not the case here. The Administrator's Allina I decision is precisely the type of post-hoc rationalization that Chenery says cannot be substituted on appeal for contemporaneous, reasoned decision-making. Chenery, 318 U.S. at 92-95.

The dangers of post-hoc rationalizations for agency action are that the judiciary, rather than the agency, will supply the reasons underlying the action and that the "real reasons for agency action will escape judicial scrutiny altogether." Women Involved in Farm Econ. v. U.S. Dep't of. Agric., 876 F.2d 994, 1000 (D.C. Cir. 1989). These concerns are not present here. Here, the agency has supplied its reasons on multiple occasions, including the Administrator's recent decision and the 2013 Rulemaking. This is also not a case where the agency's reasoning will escape judicial review given that the issue has been before the courts on multiple occasions, as demonstrated in this opinion. See infra, 29-30.

Viewing the situation in its entirety, the Court concludes that the process underlying the 2012 DSH Calculations was not arbitrary and capricious. Although the agency gave no explicit contemporaneous explanation, the concerns for post-hoc rationalization are not present. The agency had made its interpretation of the statute clear in the 2004 Final Rule, although that rule was later vacated, and the 2013 Regulation, and

has also subsequently made it clear in the Administrator's decision. Although no explanation accompanied the 2012 DSH Calculations, it is not difficult to understand the agency's reasoning, there is no concern that subsequent rationalizations are substituting contemporaneous reasoned decisionmaking, nor is there a concern that the judiciary is providing the reasons for the agency's action, rather than the agency.

Turning to Plaintiffs' second allegation that the Secretary's interpretation is inconsistent with the statute, our Court of Appeals has already held that the statutory text does not foreclose the Secretary's interpretation. Ne. Hosp. Corp., 657 F.3d at 13. In evaluating the same question of whether Part C enrollees are entitled to benefits under Part A, the Northeast Hospital court stated, at step 1 of the Chevron analysis, that "Congress ha[d] not clearly foreclosed the Secretary's interpretation that [Part C] enrollees are entitled to benefits under Part A." Id. While Northeast Hospital found that the Secretary's interpretation was not foreclosed by the statute, it did not reach the Chevron step 2 analysis to determine if the Secretary's interpretation was reasonable. See Ne. Hosp. Corp., 657 F.3d at 13. The Northeast Hospital court held that it was for the Secretary, not the Court, to determine the proper interpretation. Id. That is precisely what the Secretary has done in this instance.

In Catholic Health Initiatives v. Sebelius, the Court considered the phrase "entitled to benefits under Part A," also key to the case at hand, though not in the context of Part C days. 718 F.3d 914, 917 (2013). The Secretary argues that the Court's decision in Catholic Health is instructive here, Def.'s Mot. at 32, as the

Court deferred under Chevron step 2 to the Secretary's interpretation that "entitlement" is "simply a matter of meeting the statutory criteria, not a matter of receiving payment." Catholic Health, 718 F.3d at 919-920.

Plaintiffs offer no meaningful distinction between the case at hand and Catholic Health. See Pls.' Reply at 30-31, 39. Although the type of days specifically at issue are different, the core dispute is the same. Defendant argues that "entitlement" refers simply to meeting the statutory requirements, Def.'s Mot at 31, while Plaintiffs argue that "entitlement" requires the ability to be paid under Part A. Pls.' Reply at 3, 39-40. The Catholic Health Court deferred to the agency's interpretation, and that deference is applicable to this case as well.

In light of our Court of Appeals' decisions in Northeast Hospital and Catholic Health, as well as the narrow standard of review, the Court concludes that the Secretary's interpretation that patients enrolled in Part C continue to be "eligible" for Part A is well within her authority and not arbitrary and capricious.

IV. Conclusion

For the foregoing reasons, Plaintiffs' Motion for Summary Judgment shall be denied and Defendant's Motion for Summary Judgment shall be granted. An Order shall accompany this Memorandum Opinion.

Aug. 17, 2016 /s/ GLADYS KESSLER
GLADYS KESSLER
United States District Judge

Copies to: attorneys on record via ECF

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 14-1415 (GK)

ALLINA HEALTH SERVICES, ET AL., PLAINTIFFS

v.

SYLVIA M. BURWELL, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEFENDANT

[Filed: Aug. 17, 2016]

ORDER

Plaintiffs Allina Health Services, et al. ("Plaintiffs") are nine hospitals that bring this action against Sylvia M. Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services ("Secretary" or "Defendant"). They challenge the calculation of certain disproportionate share hospital payments as procedurally and substantively invalid.

This matter is before the Court on the Plaintiff's Motion for Summary Judgment [Dkt. No. 8] and Defendant's Cross-Motion for Summary Judgment [Dkt. No. 28]. Upon consideration of the Motions, Oppositions, Replies, the entire record herein, and for the reasons set forth in the accompanying Memorandum Opinion, it is hereby

ORDERED, that Plaintiffs' Motion for Summary Judgment is **denied**; and it is further

ORDERED, that Defendant's Motion for Summary Judgment is **granted.**

Aug. 17, 2016 /s/ GLADYS KESSLER
GLADYS KESSLER
United States District Judge

Copies to: attorneys on record via ECF

APPENDIX D

**DEPARTMENT OF HEALTH
AND HUMAN SERVICES
PROVIDER REIMBURSEMENT
REVIEW BOARD
2520 Lord Baltimore Drive, Suite L
Baltimore MD 21244-2670**

Internet: www.cms.gov/PRRBReview

**Phone: 410-786-2671
FAX: 410-786-5298**

Refer to: 14-3736G, 14-3813GC
Certified Mail [Aug. 13, 2014]

Stephanie A. Webster, Esq.
Akin, Gump, Strauss, Hauer & Feld
Robert S. Strauss Building
1333 New Hampshire Avenue, NW
Washington, DC 20036-1564

RE: Akin Gump 2012 Post-Allina Decision Medicare Part C Days Group, Provider Nos. Various, FY 2012, PRRB Case No. 14-3736G
Allina Health 2012 Post-Allina Decision Medicare Part C Days, Provider Nos. Various, FY 2012, PRRB Case No. 14-3813GC

Dear Ms. Webster:

The Provider Reimbursement Review Board (Board) has reviewed the Providers' July 17, 2014 request for expedited judicial review (EJR) (received July 18, 2014) in case number 14-3736G and the July 25, 2014 EJR request (received July 28, 2014) in case number 14-3813GC.

The Board decision granting the request for EJR is set forth below.

Issue before the Board

The issue before the Board in these cases is whether "enrollees in [Medicare] Part C are 'entitled to benefits' under Part A, such that they should be counted in the Medicare [Part A/SSI] fraction [of the disproportionate share (DSH) adjustment], or whether, if not regarded as 'entitled to benefits under Part A,' they should instead be included in the Medicaid fraction of the DSH adjustment."[1]

Background on Medicare Part C

Medicare Health Maintenance Organizations and the Medicare Advantage Program[2, 3]

The Medicare program permits its beneficiaries to receive services from managed care entities. The managed care statute implementing payments to health

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[1] Providers' Requests for EJR at 4.

[2] *See http://www.medicare.gov/glossary/m.html.* (A Medicare Advantage Plan is a type of Medicare health plan offered by a private company that contracts with Medicare to provide beneficiaries with all Part A and Part B benefits. Medicare Advantage Plans include Health Maintenance Organizations, Preferred Provider Organizations, Private Fee-for-Service Plans, Special Needs Plans, and Medicare Medical Savings Account Plans. If a beneficiary is enrolled in a Medicare Advantage Plan, Medicare services are covered through the plan and are not paid for under Original Medicare. Most Medicare Advantage Plans offer prescription drug coverage.) (last visited August 4, 2014).

[3] *See http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/* (The [Medicare + Choice (M+C)] program in Part C of Medicare was renamed the Medicare Advantage (MA) Program under the Medicare Prescription Drug, Improvement, and Modernization Act

maintenance organizations (HMOs) and competitive medical plans (CMPs) is found at 42 U.S.C. § 1395mm. The statute at 42 U.S.C. § 1395mm(a)(5) provides for "payment to the eligible organization under this section for individuals enrolled under this section with the organization and entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter . . . ." Inpatient hospital days for Medicare beneficiaries enrolled in HMOs and CMPs prior to 1999 are referred to as Medicare HMO patient care days. In the September 4, 1990 Federal Register, the Secretary[4] stated that:

> Based on the language of section 1886(d)(5)(F)(vi) of the Act [42 U.S.C. § 1395ww(d)(5)(F)(vi)], which states that the disproportionate share adjustment computation should include "patients who were entitled to benefits under Part A," we believe it is appropriate to include the days associated with Medicare patients who receive care at a qualified HMO. Prior to December 1, 1987, we were not able to isolate the days of care associated with Medicare patients in HMOs, and therefore, were unable to fold this number into the calculation [of the DSH adjustment]. However, as of December 1, 1987, a field was included on the Medicare Provider Analysis and Review (MEDPAR) file that allows us to isolate those HMO days that were associated with Medicare patients. Therefore, since that time we have

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of 2003 (MMA), which was enacted in December 2003. The MMA further established the Medicare prescription drug benefit (Part D) program, and amended the Part C program to allow most MA plans to offer prescription drug coverage.) (last visited August 4, 2014).

[4] of Health and Human Services.

> been including HMO days in the SSI/Medicare percentage [of the DSH adjustment].[5]

At that time, Medicare Part A paid for HMO services and patients continued to be eligible for Part A.[6]

With the creation of Medicare Part C in 1997,[7] Medicare beneficiaries who opted for managed care coverage under Medicare Part C were no longer entitled to have payment made for their care under Part A. Consistent with the statutory change, CMS did not include Medicare Part C days in the SSI ratios used by the intermediaries to calculate DSH payments for the FY 2001-2004.[8]

No further guidance regarding the treatment of Part C days in the DSH calculation was provided until the Federal fiscal year (FFY) 2004 Inpatient Prospective Payment System (IPPS) proposed rules were published in the May 9, 2003 Federal Register. In that notice the Secretary stated that:

> . . . an individual is eligible to elect an M+C plan if he or she is entitled to Medicare Part A and enrolled in Part B. However, once a beneficiary has

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[5] 55 Fed. Reg. 35,990, 39,994 (September 4, 1990).

[6] *Id.*

[7] The Medicare Part C program did not begin operating until January 1, 1999. *See* P.L. 105-33, 1997 HR 2015, *codified as* 42 U.S.C. § 1394w-21 Note (c) "Enrollment Transition Rule.—An individual who is enrolled [in Medicare] on December 31 1998, with an eligible organization under . . . [42 U.S.C. 1395mm] shall be considered to be enrolled with that organization on January 1, 1999, under part C of Title XVIII . . . if that organization as a contract under that part for providing services on January 1, 1999 . . . ."

[8] 69 Fed. Reg. 48,918, 49,099 (August 11, 2004).

> elected to join an M+C plan, that beneficiary's benefits are no longer administered under Part A . . . . *once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should not be included in the Medicare fraction of the DSH patient percentage. These patient days should be included in the count of total patient days in the Medicaid fraction (the denominator), and the patient's days for the M+C beneficiary who is also eligible for Medicaid would be included in the numerator of the Medicaid fraction.*[9]

The Secretary purportedly changed her position in the FFY 2005 IPPS final rule, by noting she was "revising our regulations at [42 C.F.R] § 412.106(b)(2)(i) to include the days associated with [M+C] beneficiaries in the Medicare fraction of the DSH calculation."[10] In response to a comment regarding this change, the Secretary explained that:

> . . . *we do agree that once Medicare beneficiaries elect Medicare Part C coverage, they are still, in some sense, entitled to benefits under Medicare Part A.* We agree with the commenter that these days should be included in the Medicare fraction of the DSH calculation. Therefore, we are *not adopting as final our proposal stated in the May 19, 2003 proposed rule to include the days associated with M+C beneficiaries in the Medicaid fraction. Instead, we are adopting a policy to include the patient days for M+C beneficiaries in the Medicare fraction* . . . . if the beneficiary is also an SSI

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[9] 68 Fed. Reg. 27,154, 27,208 (May 19, 2003) (emphasis added)

[10] 69 Fed. Reg. 49,098, 49,099 (August 11, 2004).

> recipient, the patient days will be included in the numerator of the Medicare fraction.[11]

Although change in policy regarding 42 C.F.R. § 412.106(b)(2)(B) was included in the August 11, 2004 Federal Register, no change to the regulatory language was published until the FFY 2008 final rule was published in the August 22, 2007 Federal Register.[12] In that publication the Secretary noted that no regulatory change had in fact occurred, and announced that she had made "technical corrections" to the regulatory language consistent with the change announced in the FFY 2005 IPPS final rule, published in the August 11, 2004 Federal Register. As a result, Part C days were required to be included in the Medicare fraction as of October 1, 2004. In this Federal Register notice the Secretary stated that:

> In the FY 2005 IPPS final rule (69 FR 49099), we discussed in the preamble our policy change to reflect the inclusion of the days associated with Medicare+ Choice (now Medicare Advantage) beneficiaries under Medicare Part C in the Medicare fraction of the DSH calculation. In that rule, we indicated that we were revising the regulation text at [42 C.F.R] § 412.106(b)(2)(i) to incorporate this policy. However, we inadvertently did not make a change in the regulation text to conform to the preamble language. We also inadvertently did not propose to change § 412.106(b)(2)(iii) in the FY 2005 final rule, although we intended to do so. Section 412.106(b)(2)(i) of the regulations discusses the numerator of the Medicare

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[11] *Id. (emphasis added)*

[12] 72 Fed. Reg. 47,130, 47,384 (August 22, 2007).

fraction of the Medicare disproportionate patient percentage (DPP) calculation while § 412.106(b)(2)(iii) of the regulations discusses the denominator of the Medicare fraction of the Medicare DPP. We intended to amend the regulation text with respect to both the numerator and the denominator of the Medicare fraction of the Medicare DPP. Therefore, in this final rule with comment period, we are making this technical correction to § 412.106(b)(2)(i) and to § 412.106(b)(2)(iii) to make them consistent with the preamble language of the FY 2005 IPPS final rule and to effectuate the policy iterated in that rule.

With respect to the technical correction that we are making to § 412.106(b)(2)(iii), we note that we ordinarily publish a notice of proposed rulemaking in the Federal Register to provide for a period for public comment before a provision such as this would take effect. However, we can waive this procedure if an agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the notice issued. We find it unnecessary to undertake notice and comment rulemaking in this instance for the additional change to § 412.106(b)(2)(iii) because this notice merely provides technical corrections to the regulations and does not make any substantive changes to the regulations or our existing policy. Therefore, under 5 U.S.C. 533(b)(B), for good cause, we waive notice and comment procedures.[13]

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[13] *Id.*

Federal Court Decisions in *Allina Health Services v. Sebelius (Allina)*[14]

In the District Court decision in *Allina* the Court concluded that the Secretary's interpretation of the fractions used in the DSH calculation and not added to the Code of Federal Regulations until the summer of 2007 (FFY 2008) were not a logical outgrowth of the notice of proposed rulemaking in 2003. In fact, the Secretary's actions were a 180-degree shift in position and a reasonable person would not have understood that such a conclusion would be reached. The Court found that the 2003 notice of proposed rulemaking did not provide adequate notice of the interpretation of the DSH fraction adopted by the Secretary in 2004 in violation of the Administrative Procedures Act and Medicare Act. The Court determined that vacatur was appropriate because the Secretary did not validly change her interpretation of the DSH calculation prior to 2007 and ordered recalculation without using the interpretation in the 2004 rule.[15]

On appeal, the D.C. Circuit Court[16] affirmed the vacatur, but determined that remanding for payment without using the 2004 Final Rule was not correct. Rather than telling the Secretary how to calculate the hospitals' reimbursement, the case should have been remanded with the error identified. The Circuit Court limited its ruling to finding that the change to the policy was not a logical outgrowth of the proposed rule. The Secretary had argued that she might obtain the same

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[14] 904 F. Supp. 2d 75 (D.D.C. 2012)

[15] *Id.* at 95.

[16] 746 F.3d. 1102 (D.C. Cir. 2014).

result [application of the invalid rule] through adjudication and since that issue was not before the court, the district court erred in ordering recalculation.[17]

Providers' Requests for EJR

The Providers explain that they were all participants in the *Allina* cases[18] discussed above in which the Federal courts vacated the Secretary's 2004 change to the treatment of Medicare Part C days in the DSH calculation. The Providers were all reimbursed by applying the regulation that was invalidated by the Courts. They are seeking an expeditious ruling on whether the rule remains valid and applicable after the *Allina* decisions or whether the Secretary's actions constitutes unlawful nonacquiecence of binding D.C. Circuit law and a violation of statutory procedural requirements. The Providers do not believe the Board has the authority to grant the relief sought.

The Providers note that in 2013 the Secretary recalculated the Part A/SSI fractions for FFYs 2010 and 2011 for all hospitals nationwide to include Part C days. However, in accordance with the Court's vacatur of the 2004 rule, the Secretary calculated revised fractions for the Providers that excluded the Part C days consistent with the pre-2004 policy. In addition, while *Allina* was pending in the courts, the Secretary engaged in rule making by issuing a new notice and comment stating

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[17] *Id.* at 1111.

[18] Generally, the *Allina* cases heard in the District of Columbia district and circuit courts involve the FFYs 2007 and 2008. The current cases involve later FFYs.

that the agency proposed to readopt the policy of counting Part C days in the Medicare fraction.[19]

Although the time for the Secretary to file a petition for *certiorari* from the *Allina* decision expired June 30, 2014, the Secretary has not issued a notice acquiescing in the D.C. Circuit Court's vacatur. In mid-June of 2014, the agency published the Part A/SSI fractions for 2012, including Part C days for all hospitals. The Providers notified the Secretary of their view that the inclusion of Part C days in the Medicare fraction violated the D.C. Circuit court's decision and new fractions should be calculated. The Providers indicate the Secretary responded that new fractions would not be calculated. The Providers contend that the vacatur restores the previously governing policy until there is a change through valid rulemaking.

Decision of the Board

The Board finds that EJR is appropriate for the issue under dispute in these cases. 42 U.S.C. § 1395oo(f)(1) and 42 C.F.R. § 405.1842 permit expedited judicial review where the Board determines that has jurisdiction over the appeal but it does not have the authority to decide a question of law, regulation or CMS ruling. In this case, the Providers are challenging the whether "enrollees in [Medicare] Part C are 'entitled to benefits' under Part A, such that they should be counted in the Medicare [Part A/SSI] fraction [of the DSH adjustment], or whether, if not regarded as 'entitled to bene-

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[19] *See* 78 Fed. Reg. 50,496, 50,615 (August 19, 2013).

fits under Part A,' they should instead be included in the Medicaid fraction of the DSH adjustment."[20]

The Board has reviewed the submissions of the Providers pertaining to the request for hearing and expedited judicial review. The Intermediary did not oppose the request for EJR. The documentation shows that the estimated amount in controversy exceeds $50,000 for a group appeal and the appeals were timely filed. In addition, the Providers protested the issue on their as-filed cost reports as required by 42 C.F.R. § 405.1835(a)(1)(ii).

The Board finds that:

1) it has jurisdiction over the matter for the subject year and the Providers are entitled to a hearing before the Board;

2) based upon the Providers' unopposed assertions regarding the Medicare Part C issue and the Secretary's actions subsequent to the decision in *Allina*, there are no findings of fact for resolution by the Board;

3) it is bound by the regulation; and

4) it is without the authority to decide the legal question of whether the regulation regarding the treatment of Medicare Part C days is valid and whether the Secretary's actions subsequent to the decision in *Allina* are legal.

Accordingly, the Board finds that the Medicare Part C days issue properly falls within the provisions of 42 U.S.C. § 1395oo(f)(1) and hereby grants the Provid-

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[20] Providers' Requests for EJR at 4.

er's request for expedited judicial review for the issue and the subject year. The Provider has 60 days from the receipt of this decision to institute the appropriate action for judicial review. Since this is the only issue under dispute, the Board hereby closes the cases.

Board Members Participating

Michael W. Harty
Clayton J. Nix, Esq.
L. Sue Andersen, Esq.

FOR THE BOARD:
/s/ MICHAEL W. HARTY
MICHAEL W. HARTY
Chairman

Enclosures: 42 U.S.C. § 1395oo(f)(1), Schedules of Providers

cc: Kyle Browning, NGS (w/Schedules of Providers)
Danene Hartley, NGS (w/Schedule of Providers)
Kevin Shanklin, BCBSA (w/Schedule of Providers)

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Schedule of Providers in Group

Group Name: Akin Group 2012 Post-Allina Decision Medicare Part C Days Group

Page No. 1 of 2

Representative: Akin Gump Strauss Hauer & Feld LLP

Date Prepared 7/14/2014

Case No: 14-3726G

Issue: Whether Medicare Part C days were properly treated in the calculation of the Medicare DSH payment.

Lead Intermediary: National Government Services

	Provider Number	Provider Name	Intermediary	FYE	A Date of Final Determination	B Date Hearing Rqst Filed	C No. of Days	D Audit Adj No.	E Amount of Reimbursement	F Original Case No.	G Date Add/ Transfer Filed
1	10-0128	Tampa General Hospital (Tampa, Hillsborough, FL)	First Coast Service Options - FL	9/30/2013	5/1/2014^	7/1/2014	122	N/A	$1,543,359	Direct Add	7/1/2014
2	33-0059	Montefiore Medical Center (Bronx, Bronx, NY)	National Government Services	12/31/2012	6/3/2014^	7/1/2014	28	N/A	$15,080,768	Direct Add	7/1/2014
3	10-0034	Mount Sinai Medical Center (Miami Beach, Dade, FL)	First Coast Service Options - FL	12/31/2012	5/28/2014^	7/8/2014	41	N/A	$4,717,393	Direct Add	7/8/2014
4	33-0055	New York Hospital Queens (Flushing, Queens, NY)	National Government Services	12/31/2012	6/5/2014^	7/8/2014	33	N/A	$7,932,982	Direct Add	7/8/2014
5	33-0256	New York Methodist Hospital (Brooklyn, Kings, NY)	National Government Services	12/31/2012	6/5/2014^	7/8/2014	33	N/A	$7,333,087	Direct Add	7/8/2014

^ There is no final determination. This date is one year from the date of cost report receipt, which is when the 180 day appeal clock starts to run.

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Schedule of Providers in Group

Group Name: Alda Group 2012 Post-Allina Decision Medicare Part C Days Group — Page No. 2 of 2

Representative: Alda Group/ Stevens Hazzer & Feld LLP — Date Prepared 7/11/2014

Case No: 14-3726G

Issue: Whether Medicare Part C days were properly treated in the calculation of the Medicare DSH payment.

Lead Intermediary: National Government Services

Provider Number	Provider Name	Intermediary	FYE	A Date of Final Determination	B Date Hearing Req Filed	C No. of Days	D Audit Adj No.	E Amount of Reimbursement	F Original Case No.	G Date Add/ Transfer Filed
6 33-0101	New York Presbyterian Hospital (New York, New York, NY)	National Government Services	12/31/2012	6/3/2014[A]	7/14/2014	41	N/A	$8,537,575	Direct Add	7/14/2014

Total Amount of Reimbursement: $45,115,060

[A] There is no final determination. This date is one year from the date of cost report receipt, which is when the 180 day appeal clock starts to run.

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Schedule of Providers in Group

Group Name: Allina Health 2012 Post-Allina Decision Medicare Part C Days Group

Page No. 1 of 1

Representative: Akin Gump Strauss Hauer & Feld LLP

Date Prepared 7/25/2014

Case No: Not Yet Assigned 14-3813GC

Issue: Whether Medicare Part C days were wrongly treated in the calculation of the Medicare DSH payment.

Lead Intermediary: National Government Services

Provider Number	Provider Name	Intermediary	FYE	A Date of Final Determination	B Date Hearing Rqst Filed	C No. of Days	D Audit Adj No.	E Amount of Reimbursement	F Original Case No.	G Date Add/ Transfer Filed
1 24-0056	United Hospital (St. Paul, Ramsey, MN)	National Government Services	12/31/2012	6/3/2014*	7/25/2014	52	N/A	$812,946	Direct Add	7/25/2014
2 24-0057	Abbott Northwestern Hospital (Minneapolis, Hennepin, MN)	National Government Services	12/31/2012	5/24/2014*	7/25/2014	62	N/A	$1,948,054	Direct Add	7/25/2014
3 24-0132	Unity Hospital (Fridley, Anoka, MN)	National Government Services	12/31/2012	5/24/2014*	7/25/2014	62	N/A	$613,541	Direct Add	7/25/2014

Total Amount of Reimbursement: $3,374,541

*There is no final determination. This date is one year from the date of cost report receipt, which is when the 120 day appeal clock starts to run.

APPENDIX E

**DEPARTMENT OF HEALTH
AND HUMAN SERVICES
PROVIDER REIMBURSEMENT
REVIEW BOARD
2520 Lord Baltimore Drive, Suite L
Baltimore MD 21244-2670**

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14-3813GC. The Board decision granting the request for EJR is set forth below.

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Background on Medicare Part C

Medicare Health Maintenance Organizations and the Medicare Advantage Program[2, 3]

The Medicare program permits its beneficiaries to receive services from managed care entities. The managed care statute implementing payments to health

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[1] Providers' Requests for EJR at 4.

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[3] See *http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/* (The [Medicare + Choice (M+C)] program in Part C of Medicare was renamed the Medicare Advantage (MA) Program under the Medicare Prescription Drug, Improvement, and Modernization Act

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> Based on the language of section 1886(d)(5)(F)(vi) of the Act [42 U.S.C. § 1395ww(d)(5)(F)(vi)], which states that the disproportionate share adjustment computation should include "patients who were entitled to benefits under Part A," we believe it is appropriate to include the days associated with Medicare patients who receive care at a qualified HMO. Prior to December 1, 1987, we were not able to isolate the days of care associated with Medicare patients in HMOs, and therefore, were unable to fold this number into the calculation [of the DSH adjustment]. However, as of December 1, 1987, a field was included on the Medicare Provider Analysis and Review (MEDPAR) file that allows us to isolate those HMO days that were associated with Medicare patients. Therefore, since that time we have been including

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[4] of Health and Human Services.

> HMO days in the SSI/Medicare percentage [of the DSH adjustment].[5]

At that time, Medicare Part A paid for HMO services and patients continued to be eligible for Part A.[6]

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[6] *Id.*

[7] The Medicare Part C program did not begin operating until January 1, 1999. *See* P.L. 105-33, 1997 HR 2015, *codified as* 42 U.S.C. § 1394w-21 Note (c) "Enrollment Transition Rule.—An individual who is enrolled [in Medicare] on December 31 1998, with an eligible organization under . . . [42 U.S.C. 1395mm] shall be considered to be enrolled with that organization on January 1, 1999, under part C of Title XVIII . . . if that organization as a contract under that part for providing services on January 1, 1999 . . . ."

[8] 69 Fed. Reg. 48,918, 49,099 (August 11, 2004).

> elected to join an M+C plan, that beneficiary's benefits are no longer administered under Part A . . . . *once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should not be included in the Medicare fraction of the DSH patient percentage. These patient days should be included in the count of total patient days in the Medicaid fraction (the denominator), and the patient's days for the M+C beneficiary who is also eligible for Medicaid would be included in the numerator of the Medicaid fraction.*[9]

The Secretary purportedly changed her position in the FFY 2005 IPPS final rule, by noting she was "revising our regulations at [42 C.F.R] § 412.106(b)(2)(i) to include the days associated with [M+C] beneficiaries in the Medicare fraction of the DSH calculation."[10] In response to a comment regarding this change, the Secretary explained that:

> . . . *we do agree that once Medicare beneficiaries elect Medicare Part C coverage, they are still, in some sense, entitled to benefits under Medicare Part A.* We agree with the commenter that these days should be included in the Medicare fraction of the DSH calculation. Therefore, we are *not adopting as final our proposal stated in the May 19, 2003 proposed rule to include the days associated with M+C beneficiaries in the Medicaid fraction. Instead, we are adopting a policy to include the patient days for M+C beneficiaries in the Medicare fraction* . . . . if the beneficiary is also an SSI recipient, the patient

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[10] 69 Fed. Reg. 49,098, 49,099 (August 11, 2004).

> days will be included in the numerator of the Medicare fraction.[11]

Although change in policy regarding 42 C.F.R § 412.106(b)(2)(B) was included in the August 11, 2004 Federal Register, no change to the regulatory language was published until the FFY 2008 final rule was published in the August 22, 2007 Federal Register.[12] In that publication the Secretary noted that no regulatory change had in fact occurred, and announced that she had made "technical corrections" to the regulatory language consistent with the change announced in the FFY 2005 IPPS final rule, published in the August 11, 2004 Federal Register. As a result, Part C days were required to be included in the Medicare fraction as of October 1, 2004. In this Federal Register notice the Secretary stated that:

> In the FY 2005 IPPS final rule (69 FR 49099), we discussed in the preamble our policy change to reflect the inclusion of the days associated with Medicare+ Choice (now Medicare Advantage) beneficiaries under Medicare Part C in the Medicare fraction of the DSH calculation. In that rule, we indicated that we were revising the regulation text at [42 C.F.R.] § 412.106(b)(2)(i) to incorporate this policy. However, we inadvertently did not make a change in the regulation text to conform to the preamble language. We also inadvertently did not propose to change § 412.106(b)(2)(iii) in the FY 2005 final rule, although we intended to do so. Section 412.106(b)(2)(i) of the regulations discusses the numerator of the Medicare

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[11] *Id. (emphasis added)*

[12] 72 Fed. Reg. 47,130, 47,384 (August 22, 2007).

fraction of the Medicare disproportionate patient percentage (DPP) calculation while § 412.106(b)(2)(iii) of the regulations discusses the denominator of the Medicare fraction of the Medicare DPP. We intended to amend the regulation text with respect to both the numerator and the denominator of the Medicare fraction of the Medicare DPP. Therefore, in this final rule with comment period, we are making this technical correction to § 412.106(b)(2)(i) and to § 412.106(b)(2)(iii) to make them consistent with the preamble language of the FY 2005 IPPS final rule and to effectuate the policy iterated in that rule.

With respect to the technical correction that we are making to § 412.106(b)(2)(iii), we note that we ordinarily publish a notice of proposed rulemaking in the Federal Register to provide for a period for public comment before a provision such as this would take effect. However, we can waive this procedure if an agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the notice issued. We find it unnecessary to undertake notice and comment rulemaking in this instance for the additional change to § 412.106(b)(2)(iii) because this notice merely provides technical corrections to the regulations and does not make any substantive changes to the regulations or our existing policy. Therefore, under 5 U.S.C. 533(b)(B), for good cause, we waive notice and comment procedures.[13]

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[13] *Id.*

Federal Court Decisions in *Allina Health Services v. Sebelius (Allina)*[14]

In the District Court decision in *Allina* the Court concluded that the Secretary's interpretation of the fractions used in the DSH calculation and not added to the Code of Federal Regulations until the summer of 2007 (FFY 2008) were not a logical outgrowth of the notice of proposed rulemaking in 2003. In fact, the Secretary's actions were a 180-degree shift in position and a reasonable person would not have understood that such a conclusion would be reached. The Court found that the 2003 notice of proposed rulemaking did not provide adequate notice of the interpretation of the DSH fraction adopted by the Secretary in 2004 in violation of the Administrative Procedures Act and Medicare Act. The Court determined that vacatur was appropriate because the Secretary did not validly change her interpretation of the DSH calculation prior to 2007 and ordered recalculation without using the interpretation in the 2004 rule.[15]

On appeal, the D.C. Circuit Court[16] affirmed the vacatur, but determined that remanding for payment without using the 2004 Final Rule was not correct. Rather than telling the Secretary how to calculate the hospitals' reimbursement, the case should have been remanded with the error identified. The Circuit Court limited its ruling to finding that the change to the policy was not a logical outgrowth of the proposed rule. The Secretary had argued that she might obtain the same

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[14] 904 F. Supp. 2d 75 (D.D.C. 2012)

[15] *Id.* at 95.

[16] 746 F.3d 1102 (D.C. Cir. 2014).

result [application of the invalid rule] through adjudication and since that issue was not before the court, the district court erred in ordering recalculation.[17]

Providers' Requests for EJR

The Providers explain that they were all participants in the *Allina* cases[18] discussed above in which the Federal courts vacated the Secretary's 2004 change to the treatment of Medicare Part C days in the DSH calculation. The Providers were all reimbursed by applying the regulation that was invalidated by the Courts. They are seeking an expeditious ruling on whether the rule remains valid and applicable after the *Allina* decisions or whether the Secretary's actions constitutes unlawful nonacquiecence of binding D.C. Circuit law and a violation of statutory procedural requirements. The Providers do not believe the Board has the authority to grant the relief sought.

The Providers note that in 2013 the Secretary recalculated the Part A/SSI fractions for FFYs 2010 and 2011 for all hospitals nationwide to include Part C days. However, in accordance with the Court's vacatur of the 2004 rule, the Secretary calculated revised fractions for the Providers that excluded the Part C days consistent with the pre-2004 policy. In addition, while *Allina* was pending in the courts, the Secretary engaged in rule making by issuing a new notice and comment stating

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[17] *Id.* at 1111.

[18] Generally, the *Allina* cases heard in the District of Columbia district and circuit courts involve the FFYs 2007 and 2008. The current cases involve later FFYs.

that the agency proposed to readopt the policy of counting Part C days in the Medicare fraction.[19]

Although the time for the Secretary to file a petition for *certiorari* from the *Allina* decision expired June 30, 2014, the Secretary has not issued a notice acquiescing in the D.C. Circuit Court's vacatur. In mid-June of 2014, the agency published the Part A/SSI fractions for 2012, including Part C days for all hospitals. The Providers notified the Secretary of their view that the inclusion of Part C days in the Medicare fraction violated the D.C. Circuit court's decision and new fractions should be calculated. The Providers indicate the Secretary responded that new fractions would not be calculated. The Providers contend that the vacatur restores the previously governing policy until there is a change through valid rulemaking.

Decision of the Board

The Board finds that EJR is appropriate for the issue under dispute in these cases. 42 U.S.C. § 1395oo(f)(1) and 42 C.F.R. § 405.1842 permit expedited judicial review where the Board determines that has jurisdiction over the appeal but it does not have the authority to decide a question of law, regulation or CMS ruling. In this case, the Providers are challenging the whether "enrollees in [Medicare] Part C are 'entitled to benefits' under Part A, such that they should be counted in the Medicare [Part A/SSI] fraction [of the DSH adjustment], or whether, if not regarded as 'entitled to bene-

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[19] *See* 78 Fed. Reg. 50,496, 50,615 (August 19, 2013).

fits under Part A,' they should instead be included in the Medicaid fraction of the DSH adjustment."[20]

The Board has reviewed the submissions of the Providers pertaining to the request for hearing and expedited judicial review. The Intermediary did not oppose the request for EJR. The documentation shows that the estimated amount in controversy exceeds $50,000 for a group appeal and the appeals were timely filed. In addition, the Providers protested the issue on their as-filed cost reports as required by 42 C.F.R. § 405.1835(a)(1)(ii).

The Board finds that:

1) it has jurisdiction over the matter for the subject year and the Providers are entitled to a hearing before the Board;

2) based upon the Providers' unopposed assertions regarding the Medicare Part C issue and the Secretary's actions subsequent to the decision in *Allina*, there are no findings of fact for resolution by the Board;

3) it is bound by the regulation; and

4) it is without the authority to decide the legal question of whether the regulation regarding the treatment of Medicare Part C days is valid and whether the Secretary's actions subsequent to the decision in *Allina* are legal.

Accordingly, the Board finds that the Medicare Part C days issue properly falls within the provisions of 42 U.S.C. § 1395oo(f)(1) and hereby grants the Provid-

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[20] Providers' Requests for EJR at 4.

er's request for expedited judicial review for the issue and the subject year. The Provider has 60 days from the receipt of this decision to institute the appropriate action for judicial review. Since this is the only issue under dispute, the Board hereby closes the cases.

Board Members Participating

Michael W. Harty
Clayton J. Nix, Esq.
L. Sue Andersen, Esq.

FOR THE BOARD:
/s/ MICHAEL W. HARTY
MICHAEL W. HARTY
Chairman

Enclosures: 42 U.S.C. § 1395oo(f)(1), Schedules of Providers

cc: Kyle Browning, NGS (w/Schedules of Providers)
Danene Hartley, NGS (w/Schedule of Providers)
Kevin Shanklin, BCBSA (w/Schedule of Providers)

Schedule of Providers in Group

RECEIVED
JUL 18 2014
PRRB

Group Name: Akin Group 2012 Post-Allina Decision Medicare Part C Days Group — Page No. 1 of 2

Representative: Akin Gump Strauss Hauer & Feld LLP — Date Prepared: 7/14/2014

Case No: 14-3726G

Issue: Whether Medicare Part C days were properly treated in the calculation of the Medicare DSH payment.

Lead Intermediary: National Government Services

	Provider Number	Provider Name	Intermediary	FYE	A Date of Final Determination	B Date Hearing Rqst Filed	C No. of Days	D Audit Adj No.	E Amount of Reimbursement	F Original Case No.	G Date Add/ Transfer Filed
1	10-0138	Tampa General Hospital (Tampa, Hillsborough, FL)	First Coast Service Options - FL	9/30/2012	3/1/2014*	7/1/2014	122	N/A	$1,543,559	Direct Add	7/1/2014
2	33-0059	MontiFiore Medical Center (Bronx, Bronx, NY)	National Government Services	12/31/2012	6/5/2014*	7/1/2014	28	N/A	$15,080,765	Direct Add	7/1/2014
3	10-0254	Mount Sinai Medical Center (Miami Beach, Dade, FL)	First Coast Service Options - FL	12/31/2012	5/28/2014*	7/8/2014	41	N/A	$4,717,292	Direct Add	7/8/2014
4	33-0085	New York Hospital Queens (Flushing, Queens, NY)	National Government Services	12/31/2012	6/5/2014*	7/8/2014	33	N/A	$7,302,982	Direct Add	7/8/2014
5	33-0226	New York Methodist Hospital (Brooklyn, Kings, NY)	National Government Services	12/31/2012	6/5/2014*	7/8/2014	33	N/A	$7,353,087	Direct Add	7/8/2014

*There is no final determination. This date is one year from the date of cost report receipt, which is when the 180 day appeal clock starts to run.

Schedule of Providers in Group

Group Name: Akin Gump 2012 Post-Allina Decision Medicare Part C Days Group — Page No. 2 of 2

Representative: Akin Gump Strauss Hauer & Feld LLP — Date Prepared: 7/11/2014

Case No: 14-3726G

Issue: Whether Medicare Part C days were properly counted in the calculation of the Medicare DSH payment.

Lead Intermediary: National Government Services

Provider Number	Provider Name	Intermediary	FYE	A Date of Final Determination	B Date Hearing Rqst Filed	C No. of Days	D Audit Adj No.	E Amount of Reimbursement	F Original Case No.	G Date Add/ Transfer Filed
6 33-0101	New York Presbyterian Hospital (New York, New York, NY)	National Government Services	12/31/2012	6/3/2014[A]	7/14/2014	41	N/A	$8,537,575	Direct Add	7/14/2014

Total Amount of Reimbursement: $45,115,080

[A] There is no final determination. This date is one year from the date of cost report receipt, which is when the 180 day appeal clock starts to run.

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Schedule of Providers in Group

Group Name: Allina Health 2012 Post-Allina Decision Medicare Part C Days Group

Page No. 1 of 1

Representative: Alvin Gunn Stinson Henry & Reid LLP

Date Prepared 7/25/2014

Case No: Not Yet Assigned 14-3813GC

Issue: Whether Medicare Part C days were properly treated in the calculation of the Medicare DSH payment.

Lead Intermediary: National Government Services

Provider Number	Provider Name	Intermediary	FYE	A Date of Final Determination	B Date Hearing Req Filed	C No. of Days	D Audit Adj No.	E Amount of Reimbursement	F Original Clm No.	G Date Add/ Transfer Filed
1 24-0058	United Hospital (St. Paul, Ramsey, MN)	National Government Services	12/31/2012	6/5/2014*	7/25/2014	52	N/A	$423,946	Direct Add	7/25/2014
2 24-0087	Abbott Northwestern Hospital (Minneapolis, Hennepin, MN)	National Government Services	12/31/2012	5/24/2014*	7/25/2014	62	N/A	$1,948,054	Direct Add	7/25/2014
3 24-0152	Unity Hospital (Fridley, Anoka, MN)	National Government Services	12/31/2012	5/24/2014*	7/25/2014	62	N/A	$613,341	Direct Add	7/25/2014

Total Amount of Reimbursement $3,374,341

*There is no final determination. This date is one year from the date of cost report receipt, which is when the 180 day appeal clock starts to run.

APPENDIX F

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 16-5255

ALLINA HEALTH SERVICES, DOING BUSINESS AS UNITED HOSPITAL, DOING BUSINESS AS UNITY HOSPITAL, DOING BUSINESS AS ABBOTT NORTHWESTERN HOSPITAL, ET AL., APPELLANTS

v.

ERIC D. HARGAN, ACTING SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, APPELLEE

Filed: Nov. 29, 2017

ORDER

Before: HENDERSON, KAVANAUGH, and MILLETT, *Circuit Judges.*

Upon consideration of appellee's petition for panel rehearing filed on October 4, 2017, and the response thereto, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Ken R. Meadows
Deputy Clerk

APPENDIX G

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 16-5255

ALLINA HEALTH SERVICES, DOING BUSINESS AS UNITED HOSPITAL, DOING BUSINESS AS UNITY HOSPITAL, DOING BUSINESS AS ABBOTT NORTHWESTERN HOSPITAL, ET AL., APPELLANTS

v.

ERIC D. HARGAN, ACTING SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, APPELLEE

Filed: Nov. 29, 2017

ORDER

Before: GARLAND, *Chief Judge*; HENDERSON, ROGERS, TATEL, GRIFFITH, KAVANAUGH, SRINIVASAN, MILLETT, PILLARD, and WILKINS, *Circuit Judges*.

Upon consideration of appellee's petition for rehearing en banc, the response thereto, and the absence of a request by any member of the court for a vote, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Ken R. Meadows
Deputy Clerk

APPENDIX H

1. 5 U.S.C. 551 provides in pertinent part:

Definitions

For the purposes of this subchapter—

* * * * *

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing;

(5) "rule making" means agency process for formulating, amending, or repealing a rule;

(6) "order" means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

(7) "adjudication" means agency process for the formulation of an order;

* * * * *

2. 5 U.S.C. 553 provides:

Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and

public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

3. 42 U.S.C. 1395w-21 (2012) provides in pertinent part:

Eligibility, election, and enrollment

(a) Choice of medicare benefits through Medicare+Choice plans

(1) In general

Subject to the provisions of this section, each Medicare+Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits (other than qualified prescription drug benefits) under this subchapter—

(A) through the original medicare fee-for-service program under parts A and B of this subchapter, or

(B) through enrollment in a Medicare+Choice plan under this part,

and may elect qualified prescription drug coverage in accordance with section 1395w-101 of this title.

(2) Types of Medicare+Choice plans that may be available

A Medicare+Choice plan may be any of the following types of plans of health insurance:

(A) Coordinated care plans (including regional plans)

(i) In general

Coordinated care plans which provide health care services, including but not limited to health maintenance organization plans (with or without point of service options), plans offered by

provider-sponsored organizations (as defined in section 1395w–25(d) of this title), and regional or local preferred provider organization plans (including MA regional plans).

(ii) Specialized MA plans for special needs individuals

Specialized MA plans for special needs individuals (as defined in section 1395w-28(b)(6) of this title) may be any type of coordinated care plan.

(B) Combination of MSA plan and contributions to Medicare+Choice MSA

An MSA plan, as defined in section 1395w-28(b)(3) of this title, and a contribution into a Medicare+Choice medical savings account (MSA).

(C) Private fee-for-service plans

A Medicare+Choice private fee-for-service plan, as defined in section 1395w-28(b)(2) of this title.

(3) Medicare+Choice eligible individual

(A) In general

In this subchapter, subject to subparagraph (B), the term "Medicare+Choice eligible individual" means an individual who is entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter.

(B) Special rule for end-stage renal disease

Such term shall not include an individual medically determined to have end-stage renal disease, except that—

(i) an individual who develops end-stage renal disease while enrolled in a Medicare+Choice plan may continue to be enrolled in that plan; and

(ii) in the case of such an individual who is enrolled in a Medicare+Choice plan under clause (i) (or subsequently under this clause), if the enrollment is discontinued under circumstances described in subsection (e)(4)(A) of this section, then the individual will be treated as a "Medicare+Choice eligible individual" for purposes of electing to continue enrollment in another Medicare+Choice plan.

* * * * *

4. 42 U.S.C. 1395hh (1982) provides:

Regulations

The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

5. 42 U.S.C. 1395hh (Supp. IV 1986) provides:

Regulations

(a) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(b)(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

6. 42 U.S.C. 1395hh (1988) provides:

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) **Publication of certain rules; public inspection; changes in data collection and retrieval**

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which—

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this subchapter shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1395h of this title as are necessary to make easily accessible for the Secretary and other

appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this subchapter, including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.

7. 42 U.S.C. 1395hh provides:

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publi-

cation of a proposed regulation or an interim final regulation.

(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the

applicable regular timeline under this paragraph and that provides an explanation for such failures.

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which—

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this subchapter shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1395h of this title as are necessary to make easily accessible for the Secretary and other appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this subchapter, including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.

(e)[1] Retroactivity of substantive changes; reliance upon written guidance

(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

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[1] So in original. No subsec. (d) has been enacted.

(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

(2)(A) If—

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1395zz(g) of this title) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any penalty or interest under this subchapter or the provisions of subchapter XI of this chapter insofar as they relate to this subchapter (including interest under a repayment plan under section 1395ddd of this title or otherwise) relating to the provision of such items or service or such claim if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.

(f) Report on areas of inconsistency or conflict

(1) Not later than 2 years after December 8, 2003, and every 3 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this subchapter and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect—

(A) Information from individuals entitled to benefits under part A or enrolled under part B of this subchapter, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman with respect to such areas of inconsistency and conflict; and

(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

8. 42 U.S.C. 1395ww provides in pertinent part:

Payments to hospitals for inpatient hospital services

* * * * *

(d) Inpatient hospital service payments on basis of prospective rates; Medicare Geographical Classification Review Board

* * * * *

(5)(A)(i)

* * * * *

(F)(i) Subject to subsection (r), for discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which—

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this subchapter or State plans approved under subchapter XIX of this chapter), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

* * * * *

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds—

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of—

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter and were entitled to supplementary security income benefits (excluding any State supplementation) under subchapter XVI of this chapter, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX of this chapter, but who were not entitled to benefits under part A of this subchapter, and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under subchapter XI.

* * * * *

9. 42 C.F.R. 412.106 (2003) provides in pertinent part:

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of patient days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * * *

APPENDIX I

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No.: 10-1463 (RMC)

ALLINA HEALTH SERVICES, ET AL., PLAINTIFFS

v.

SYLVIA M. BURWELL, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, DEFENDANT

DECLARATION OF ING JYE CHENG

I, Ing Jye Cheng, hereby make the following declaration:

1. I am the Director of the Division of Acute Care, Hospital and Ambulatory Care Group, Center for Medicare, Centers for Medicare & Medicaid Services ("CMS"), U.S. Department of Health and Human Services ("HHS"). I have served in this position since June 2014. I had previously served as the Deputy Director of the Division of Acute Care from March 2009 through June 2014.

2. The Center for Medicare develops payment rules and decisions, undertakes benefit category determinations, and formulates Medicare policy for the development and maintenance of new and revised codes. Within the Center for Medicare, the Hospital and Ambulatory Policy Group is responsible for developing and refining acute care hospital payment systems, as well as most outpatient and practitioner payment systems. This group contains four divisions including the Divi-

sion of Acute Care, which defines the scope of payments for Medicare benefits for services provided by acute care hospitals to inpatients, and develops, updates, and evaluates the hospital inpatient prospective payment systems ("IPPS") for payments to hospitals for inpatient services and associated capital costs.

3. I make this declaration based upon my personal knowledge and information available to me in my official capacity.

4. I am familiar with the subject matter of the above-captioned lawsuit, which involved a challenge to a regulation CMS adopted on August 11, 2004, governing the calculation of disproportionate share hospital ("DSH") payments. *See* 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004). The rule required that patients enrolled in a Medicare part C plan (Medicare Advantage) would be counted as "entitled to benefits under part A" under 42 U.S.C. § 1395ww(d)(5)(F)(iv)(I) and therefore included in the numerator of the Medicare SSI fraction. Prior to the regulation adopted on August 11, 2004, CMS had not previously addressed that question by rulemaking.

5. On November 12, 2012, this Court vacated that rule, and that decision was upheld by the Court of Appeals on April 1, 2014. CMS understands that the vacated rule has no legal effect and cannot be relied on for any purpose. Accordingly, CMS has stopped relying on the vacated rule for any purpose, and it is my understanding that CMS has verbally instructed its contractors to stop relying on the vacated rule.

6. Because of the vacatur of the rule, there is now no regulation addressing the question of whether patients enrolled in Medicare part C should be considered "entitled to benefits under part A" for purposes of applying 42 U.S.C. § 1395ww(d)(5)(F)(iv) to time periods before October 1, 2014. In the absence of a regulation interpreting the statute, CMS nevertheless must apply some interpretation of the statute in order to make DSH payments to hospitals.

7. One step in the calculation of a hospital's DSH payments for a given year is the computation of a provider's SSI fraction. This requires the matching of individual Medicare billing records (maintained by CMS) to individual SSI records (maintained by the Social Security Administration). CMS makes these SSI fractions available to Medicare Administrative Contractors ("MAC"); MACs then calculate a provider's Medicaid fraction based on data submitted by the provider and determine the disproportionate patient percentage. 42 C.F.R. § 412.106(b)(4)-(5). As part of the process for making SSI fractions available to MACs, CMS posts SSI fractions on this website. Posted SSI fractions are not final payment determinations appealable under 42 U.S.C. § 1395oo. Plaintiffs' posted 2012 SSI fractions were not calculated in reliance on the vacated rule.

8. This case has been remanded back to the Secretary for a decision regarding the calculation of plaintiffs' DSH payments that does not rely on the vacated regulation. Plaintiffs will, accordingly, receive a new decision regarding those DSH payments. If that decision is adverse to the plaintiffs, they will be able to appeal as provided for in 42 U.S.C. § 1395oo. Pending a final adjudicatory decision of the Secretary address-

ing the question of whether the days of patients enrolled in Medicare part C should be treated as "entitled to benefits under part A" when applying 42 U.S.C. § 1395ww(d)(5)(F)(iv), CMS is calculating DSH payments according to what it believes to be the most appropriate interpretation of the statute in the absence of a binding regulation on that question.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief. 28 U.S.C. § 1746. Executed this 4 day of August 2014.

/s/ ING JYE CHENG
Name

No. 17-1484

In The Supreme Court of the United States

ALEX M. AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

ALLINA HEALTH SERVICES, ET AL.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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QUESTION PRESENTED

This case concerns the Government's decision to forgo notice-and-comment rulemaking in a unique circumstance: when readopting a change in a substantive legal standard governing payment to hospitals nationwide after the D.C. Circuit had vacated a final rule attempting to adopt the same change for a logical outgrowth failure.

The Government frames the Question Presented as follows:

> Whether Section 1395hh(a)(2) requires HHS to conduct notice-and-comment rulemaking before providing instructions to a Medicare Administrative Contractor that makes initial determinations of payments due under Medicare, when those instructions rest on a non-legally-binding administrative interpretation of a relevant statutory provision.

Pet. (I).

The Government does not present any question with respect to 42 U.S.C. 1395hh(a)(4), an independent ground for the D.C. Circuit's judgment that requires notice-and-comment rulemaking before a Medicare rule vacated for a logical outgrowth failure can take effect.

PARTIES TO THE PROCEEDING

Respondents are the private non-profit hospitals identified below, who were plaintiffs in the district court and appellants in the court of appeals:

1. Allina Health System d/b/a Abbott Northwestern Hospital

2. Allina Health System d/b/a United Hospital

3. Allina Health System d/b/a Unity Hospital

4. Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital

5. Montefiore Medical Center

6. Mount Sinai Medical Center of Florida, Inc. d/b/a Mount Sinai Medical Center

7. New York - Presbyterian / Queens

8. New York Presbyterian Brooklyn Methodist Hospital

9. The New York and Presbyterian Hospital

Petitioner Alex M. Azar II, Secretary of Health and Human Services, was defendant in the district court and appellee in the court of appeals.

RULE 29.6 DISCLOSURE

Montefiore Health System and Montefiore Medicine Academic Health System, Inc. are parent companies of Montefiore Medical Center. There are no other parent companies, and no publicly held corporation owns 10 percent or more of any respondents' stock.

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In The
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ALEX M. AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES,

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ALLINA HEALTH SERVICES, ET AL.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF IN OPPOSITION

The Government's Question Presented (and the bulk of its petition) suggests that the D.C. Circuit's application of 42 U.S.C. 1395hh(a)(2) to the unique facts here was the sole basis for its judgment that notice-and-comment rulemaking was required. Not so. The D.C. Circuit explicitly found that "even if" section 1395hh(a)(2) did not require notice and comment, a distinct provision of the Medicare Act, 42 U.S.C. § 1395hh(a)(4), did. That is because the D.C. Circuit previously vacated the prior rule on the same issue for a logical outgrowth failure. The independent section 1395hh(a)(4) holding, on a matter of first impression, means the D.C. Circuit's

judgment would stand however this Court resolved the Question Presented. For that and other reasons, the petition should be denied.

STATEMENT

I. THE MEDICARE PROGRAM

A. Payment for Inpatient Hospital Services

Petitioner Secretary of Health and Human Services ("Secretary") administers the federal Medicare program, which furnishes benefits to elderly and disabled individuals. Two parts of the Medicare Act are pertinent here.

The first is Medicare part A, which covers inpatient hospital services and provides for payment to hospitals on a fee-for-service basis. 42 U.S.C. §§ 426(c), 1395d(a)(1), 1395f(a)-(b), 1395x(u). Part A payments to hospitals generally are made under a prospective payment system at predetermined, standardized rates per inpatient discharge. *Id.* § 1395ww(d); *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011). Those standard, per-case rates are subject to further adjustments to account for factors that may cause a hospital to incur greater than average costs to treat Medicare patients. 42 U.S.C. § 1395ww(d)(5). One such adjustment, reflecting the additional costs of providing services to low-income patients, is called the "disproportionate share hospital," or "DSH," payment. *Id.* § 1395ww(d)(5)(F).

The Secretary undertakes yearly notice-and-comment rulemaking on changes to the part A

prospective payment system. 42 U.S.C. § 1395ww(d)(6) (requiring Secretary to publish an annual update of the methodology and payment rates by August 1); 42 C.F.R. § 412.8 (same). This annual rulemaking takes an average of 102 days to complete. Add. 1a-3a.

The second part of the Medicare statute pertinent here is part C, created in 1997. Part C established a managed care program (currently called "Medicare Advantage," formerly "Medicare+Choice" or "M+C") that is an alternative to the part A fee-for-service program. 42 U.S.C. § 1395w-21(a). An eligible beneficiary can elect to receive benefits through enrollment in a managed care plan under part C in lieu of benefits under the part A fee-for-service program. *Id.* § 1395w-21(a)(1), (i)(1); *Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 6 (D.C. Cir. 2011).

B. The Part A DSH Payment

This case concerns the treatment of Medicare part C patients in the DSH payment calculation under the part A prospective payment system.

The part A DSH payment turns on a "disproportionate patient percentage" that is the sum of two fractions representing inpatient care furnished to low-income individuals. 42 U.S.C. § 1395ww(d)(5)(F)(v), (vi). The two fractions depend, in inverse fashion, on the number of days spent in the hospital by patients who are "entitled to benefits under [Medicare] part A." *Id.* § 1395ww(d)(5)(F)(vi)(I)-(II).

The first fraction, which the D.C. Circuit called the "Medicare fraction," measures the proportion of all patients "entitled to benefits under [Medicare] part A" who are also "entitled to supplementary security income ["SSI"]] benefits." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I). The Secretary issues Medicare fractions for each fiscal year for all hospitals nationwide that are binding on the agency, its contractors, and hospitals. *See* 42 C.F.R. § 412.106(b)(2), (5).

The second fraction, the "Medicaid" fraction, measures the proportion of the total of all patients who were Medicaid-eligible but "*not* entitled to benefits under part A." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II) (emphasis added).

Patients are either part-A-entitled or not. Accordingly, a given patient can be counted in the numerator of one fraction or the other, but not both. *Allina Health Servs. v. Sebelius*,, 746 F.3d 1102, 1108 (D.C. Cir. 2014) (*Allina I*).

C. Medicare Payment Appeals

Medicare Administrative Contractors (formerly called "fiscal intermediaries") perform part A audit and payment functions. Pet. App. 3a. A hospital must file an annual "cost report" with its contractor. 42 C.F.R. §§ 413.20, 413.24. The contractor then issues notice of the final amount of Medicare program reimbursement due the hospital for that period. *See* 42 C.F.R. § 405.1803; *see also id.* § 405.1807.

A hospital may appeal that final determination, or the contractor's failure to issue a timely final determination, to the Provider Reimbursement

Review Board ("Board"), an administrative tribunal appointed by the Secretary. 42 U.S.C. § 1395oo(a)(1), (h); 42 C.F.R. §§ 405.1835-405.1877. When the Board determines that it lacks authority to decide a question of law or regulations relevant to an appeal, hospitals have the right to immediate judicial review of the underlying agency decision. 42 U.S.C. § 1395oo(f)(1).

D. The Medicare Act's Special Notice-and-Comment Rulemaking Requirements

When it enacted the Medicare program in 1965, Congress authorized the Secretary to prescribe regulations for administering the program. Social Security Amendments of 1965, Pub. L. No. 89-97, Title I, § 102(a), 79 Stat. 286, 331 (codified at 42 U.S.C. § 1395hh(a)(1)).

In 1986, Congress mandated a 60-day notice-and-comment period for Medicare regulations subject to three limited exceptions. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9321(e)(1), 100 Stat. 1874, 2017 (codified at 42 U.S.C. §§ 1395hh(a)(1), 1395hh(b)). The exceptions are: (1) where a statute specifically permits no prior public comment or a shorter comment period; (2) where a statute specifies a rulemaking deadline that falls within 150 days of its enactment; or (3) where the good cause exemption of the Administrative Procedure Act (APA) (5 U.S.C § 553(b)(B)) is satisfied. 42 U.S.C. § 1395hh(b).

A year later, still concerned that "important policies [were] being developed without benefit of the public notice and comment period," H.R. Rep. No.

100-391(I), at 430 (1987), reprinted in 1987 U.S.C.C.A.N. 2313-1, Congress further amended the Medicare statute to establish additional, particularized notice-and-comment rulemaking requirements. Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4035, 101 Stat. 1330, 1330-78. As amended, the statute mandates that "[n]o rule, requirement, or other statement of policy *** that establishes or changes a substantive legal standard governing *** the payment for services *** shall take effect unless it is promulgated by the Secretary by regulation," 42 U.S.C. § 1395hh(a)(2), through notice-and-comment rulemaking, *id.* § 1395hh(a)(1). When "manual instructions, interpretative rules, statements of policy, and guidelines of general applicability" are not required to be promulgated through notice-and-comment rulemaking, then the Secretary must list them in the Federal Register. *Id.* § 1395hh(c)(1). *See* H.R. Rep. No. 100-495, at 563 (1987) (Conf. Rep.), reprinted in 1987 U.S.C.C.A.N. 2313-1245, 2313-1309 (describing provision as requiring publication of list of "interpretative rules" "which *** are not published *as required by* [§ 1395hh(a)(2)] above") (emphasis added)

In 2003, Congress modified the Medicare Act further to provide that "[i]f the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice," that provision "shall not take effect until there is the further opportunity for public comment and publication of the provision again as a final regulation." Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L.

No. 108-173, § 902, 117 Stat. 2066, 2375 (codified at 42 U.S.C. § 1395hh(a)(4)).

In addition, "[a] substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability *** shall not be applied *** retroactively to items and services furnished before the effective date of the change" except under circumstances not relevant here. 42 U.S.C. § 1395hh(e)(1).

II. THE SECRETARY'S NEW STANDARD ON PART C PATIENTS IN THE DSH PAYMENT AND LITIGATION CHALLENGING IT

A. The Pre-2004 Rule

This litigation stems from a 2004 rulemaking. Before 2004, the Secretary treated part C patients as *not* entitled to benefits under part A in calculating the DSH payment. *See* Pet. App. 4a ("Before 2004, HHS had *not* treated Part C enrollees as 'entitled to benefits under Part A.'") (citation omitted); *Allina I*, 746 F.3d at 1106, 1108 (Secretary "treated Part C patients as *not* entitled to benefits under Part A," "excluding Part C days from the Medicare fraction and including them in the Medicaid fraction") (citation omitted); *Northeast Hosp.*, 657 F.3d at 16-17 (2004 rule "contradicts [the Secretary's] former practice of excluding [part C] days from the Medicare fraction" as well as written agency guidance).

Specifically, the Secretary's policy and practice before 2004 reflected the original 1986 DSH regulation, which counted as Medicare part-A-entitled days only patient days that were covered and

paid under the part A fee-for-service system. *See* 42 C.F.R. § 412.106(b)(2)(i) (2003) (defining Medicare fraction to include only "the number of *covered* patient days") (emphasis added); *see also id.* § 409.3 (defining "covered" as services for which payment is authorized); 51 Fed. Reg. 16,772, 16,777 (May 6, 1986) (explaining the Secretary's intent when regulation adopted to include only "covered Medicare Part A inpatient days"). Although the 1986 regulation did not expressly mention part C patient days (as noted above, part C came later), it unambiguously excluded them as days not covered and paid under part A. *See Catholic Health Initiatives Iowa Corp. v. Sebelius*, 718 F.3d 914, 921 n.5 (D.C. Cir. 2013) (noting that the pre-2004 regulation limited the fraction to "covered Medicare Part A inpatient days").

B. The 2004 Rule Change

In 2003, the Secretary published a proposed rule "to clarify" the longstanding standard under the 1986 regulation of excluding part C days from the Medicare fraction, and including them in the Medicaid fraction, because "once a beneficiary has elected to join [a part C] plan, that beneficiary's benefits are no longer administered under Part A." 68 Fed. Reg. 27,154, 27,208 (May 19, 2003).

In a final rule published a year later, however, the Secretary engaged in a "volte-face," *Allina I*, 746 F.3d at 1109, adopting the exact opposite standard. The 2004 final rule provided that the Secretary would count days not paid by part A, including part C days, as part-A-entitled days. 69 Fed. Reg. 48,916,

49,099 (Aug. 11, 2004); *see also Allina Health Servs. v. Sebelius*, 904 F. Supp. 2d 75, 81 (D.D.C. 2012), *aff'd in part and rev'd in part*, 746 F.3d 1102 (D.C. Cir. 2014).[1] The Secretary's only explanation for the about-face was that part C patients "are still, in some sense, entitled to benefits under Medicare [p]art A." 69 Fed. Reg. at 49,099.

In an impact analysis accompanying the 2004 final rule, the Secretary predicted that the part C days standard change would not "have a significant impact on payments." 69 Fed. Reg. at 49,770. The agency said its estimate was "[b]ased on an analysis from our actuarial staff," and the impact of the new part C days policy would not exceed $50 million for one year even when combined with three other changes that were all expected to reduce DSH payments. *Id.*

C. Earlier Cases Challenging The 2004 Rule

The Secretary initially attempted to apply the new 2004 rule to DSH payments for services rendered in prior periods. The D.C. Circuit rejected that maneuver, finding the rule "change[d] the legal consequences of treating low-income patients" and

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[1] The final rule deleted the requirement that days must be "covered" by Medicare part A to be included as part-A-entitled days. *Compare* 42 C.F.R. § 412.106 (b)(2)(i) (2003) *with* § 412.106(b)(2)(i) (2004); *see also* 69 Fed. Reg. at 49,246.

thus could not be applied retroactively. *Northeast Hosp.*, 657 F.3d at 13-17.[2]

In 2009, while that case was pending, the Secretary began to apply the 2004 rule to later periods. The Secretary first applied the rule in issuing Medicare fractions for federal fiscal year 2007. A group of hospitals, including Respondents, brought a challenge alleging, *inter alia*, that the 2004 rule was not the "logical outgrowth" of the 2003 proposed rule, and was arbitrary and capricious because the agency's "cursory explanation in the 2004 Final Rule" failed to acknowledge its departure from past policy, or the "financial impact" of that change. *Allina I*, 904 F. Supp. 2d at 92-94. The Secretary's defense of the rule denied any significant economic impact of the 2004 policy change, arguing that the hospitals proffered an "outsized estimate" standing on a "faulty assumption." Def's Mot. Summ. J. at 33-34 & n.13, *Allina I*, No. 1:10-cv-1463, (D.D.C. Mar. 5, 2012), ECF No. 35. The district court agreed with the hospitals, however, and vacated the 2004 rule on both grounds. *Allina I*, 904 F. Supp. 2d at 89-93, 95.

The Secretary appealed. The hospitals again raised the Secretary's "woefully inadequate"

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[2] The hospitals there also argued that the 2004 rule was inconsistent with the DSH statute's plain terms. A divided panel disagreed. *Northeast Hosp.*, 657 F.3d at 5-13, 18-24. Concurring in the judgment, Judge Kavanaugh agreed with the hospitals that a patient who "receives Medicare benefits under Medicare Part C for a particular 'patient day'" is not "also 'entitled' for that same 'patient day' to Medicare benefits under Medicare Part A." *Id.* at 18.

consideration of the impact of the 2004 rule. Br. for Pls.-Appellees at 40, *Allina I*, No. 13-5011 (D.C. Cir. Aug. 1, 2013). This time around, the Secretary contended "this is not a case where the financial impact is readily apparent." Br. for Def.-Appellant at 44 n.6, *Allina I*, No. 13-5011 (D.C. Cir. July 1, 2013).

The D.C. Circuit affirmed on the ground that "the Secretary's final rule was not a logical outgrowth of the proposed rule." *Allina I*, 746 F.3d at 1109. The D.C. Circuit explained that "[t]he Secretary's estimated financial impact of its proposal—that there should not be a major impact associated with this proposed change—supports [the] conclusion" that the 2004 rule was not a logical outgrowth of the 2003 proposed rule. *Id.* at 1108. The D.C. Circuit did not reach the reasonableness of the Secretary's decision-making in adopting the 2004 rule. *Id.* at 1111.

The D.C. Circuit affirmed the vacatur of the rule and remanded the case to the agency, holding that "[t]he question whether the Secretary could reach the same result" on remand was not yet before it. *Id.*

More than a year and a half after the D.C. Circuit decision became final (and the agency summarily promulgated the 2012 Medicare fractions at stake here), the Secretary issued a decision on the remand in *Allina I*. *See* Def.'s Mot. For Summ. J. at Attach. No. 4, *Allina II*, No. 1:14-cv-1415 (D.D.C. Dec. 15, 2015), ECF No. 29-4. The remand decision concluded, again, that part C days should be treated as part-A-entitled days. *Id.* at 41-46. The remand decision rested on the false premise, contrary to D.C. Circuit rulings in *Northeast Hospital* and *Allina I*,

that the Secretary was continuing the same standard that was in effect before the 2004 rule change. *Id.* at 30-35. The remand decision also disclaimed that the treatment of part C patients in the DSH payment calculation had any significant financial impact. *Id.* at 43-44 & nn.93 & 94.

The hospitals in *Allina I* challenged the remand decision in a suit pending before the district court, *Allina Health Sys. v. Burwell*, No. 16-cv-00150 (D D.C. Jan. 29, 2016). That case is stayed pending the outcome of the petition here.

D. The 2013 Prospective Rule

In 2013, while the Secretary's appeal in *Allina I* was pending before the D.C. Circuit, the agency engaged in a new, prospective rulemaking on part C days in the DSH payment as part of the annual inpatient prospective payment system rulemaking for federal fiscal year 2014. 78 Fed. Reg. 50,496, 50,615 (Aug. 19, 2013). Effective October 1, 2013, the standard governing part C days in the DSH calculation reverted to the policy articulated in the now vacated 2004 rule. *See id.* at 50,619 (rule "readopt[ion]" applies to "FY 2014 and subsequent years" only). The Secretary refused again to consider the financial impact of this change from the pre-2004 standard, asserting that the agency did "not believe that there will be additional savings or costs to the Medicare program, and by inference, to hospitals, as a result of this policy." *Id.* at 50,620.

E. This Case (*Allina II*)

1. In June 2014, the Secretary published Medicare fractions for federal fiscal year 2012

applying the same standard that was adopted in the 2004 rule that the D.C. Circuit had just vacated sixteen days earlier. That issuance, which applied to every hospital nationwide, offered only a cursory note stating that the Medicare fractions included part C days. Pet. App. 5a-6a. The Secretary proceeded without notice, comment opportunity, or explanation for the departure from the reinstated pre-2004 standard under the 1986 regulation.

Respondents filed appeals to the Secretary's Board and requested expedited judicial review. C.A. Joint App. at 89-167, 178-248. The Board granted that request under 42 U.S.C. § 1395oo(f), concluding that it lacked authority to decide the legality of the part C standard embodied in the issuance of the fractions after *Allina I*. Pet. App. 56a-58a, 71a-73a.

Respondents brought suit and, in briefing at the district court, the Secretary again disavowed any clear financial impact of the part C policy. The Secretary argued it "is wrong" to think that including part C days as part A-entitled reduces DSH payments to hospitals. Gov't Reply at 12-13, 15, *Allina II*, No. 1:14-cv-1415 (D.D.C. Feb. 4, 2016), ECF No. 33.

The district court granted summary judgment to the Secretary. It found that the issuance of Medicare fractions treating part C patients as part-A entitled was an interpretative rule exempt from the APA's notice-and-comment requirement, and that Medicare Act section 1395hh(a)(2) incorporated the APA's exemption. Pet. App. 34a, 36a, 44a. The district court did not address Respondents' arguments about

the independent notice-and-comment requirement of section 1395hh(a)(4) triggered by the 2004 rule's logical outgrowth failure. Pet. App. 19a-44a.

2. The D.C. Circuit unanimously reversed.

a. The D.C. Circuit explained that the text of section 1395hh(a)(2) "describes in fairly straightforward language when notice and comment is necessary"—namely, "for any (1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services.'" Pet. App. 12a (citation omitted). The D.C. Circuit found that test "readily met here." *Id.*

First, "HHS's inclusion of Part C days in the fiscal year 2012 Medicare fractions," the D.C. Circuit reasoned, "is, at the very least, a 'requirement'" because those fractions, which must be used for DSH payment determinations, "treat Part C enrollees as 'entitled to benefits under Part A.'" Pet. App. 12a-13a (citing 42 C.F.R. § 412.106(b)(2), (5)).

Second, the 2012 issuance constituted a "change" because HHS's "baseline practice" before the invalidated 2004 rule "was to *exclude* Part C days from Medicare fractions." Pet. App. 13a (citing *Northeast Hosp.*, 657 F.3d at 15).

Third, the D.C. Circuit found that the issuance promulgated a "substantive legal standard" because the fractions "define the scope of hospitals' legal rights to payment for treating low-income patients." Pet. App. 13a-14a.

Fourth, because "[t]he fractions are used to calculate the payment that providers will receive for providing healthcare services to low-income patients," the inclusion of part C days "governs 'payment for services.'" Pet. App. 14a. Consequently, "[t]he inclusion of Part C days means that the providers will now receive lower payments." *Id.*

The D.C. Circuit did not decide whether the "decision to include Part C days in the 2012 Medicare fractions was in fact an interpretive rule." Pet. App. 15a. But it nonetheless rejected the Secretary's argument that the Medicare Act incorporates the APA's exception for interpretive rules. Pet. App. 17a. The D.C. Circuit "respectfully disagree[d]" with decisions from other circuits on that specific point. *Id.* "Unlike the APA, the text of the Medicare Act does not exempt interpretive rules from notice-and-comment rulemaking." Pet. App. 15a. "On the contrary," the court explained, "the text expressly *requires* notice-and-comment rulemaking. *** We must respect Congress's use of different language and its establishment of different notice-and-comment requirements in the Medicare Act and the APA." Pet. App. 15a-16a.

b. The D.C. Circuit ruled, in the alternative, that "even if HHS were correct that the Medicare Act somehow incorporated the APA's notice-and-comment exception for interpretive rules, HHS would still not prevail" based on another provision of the Medicare statute, section 1395hh(a)(4), that "expressly required notice and comment in this case." Pet. App. 17a. In particular, the D.C. Circuit held that section 1395hh(a)(4) precludes a regulation from "becom[ing]

legally operative until it has gone through notice-and-comment rulemaking" if it includes "a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking." Pet. App. 17a-18a (internal quotation marks and citation omitted). Further, the D.C. Circuit confirmed that "HHS could not circumvent this [Section 1395hh(a)(4)] requirement by claiming that it was acting by way of adjudication rather than rulemaking" because "[t]he statutory text says that the vacated rule may not 'take effect' at all until there has been notice and comment." Pet. App. 18a.

The D.C. Circuit denied the Secretary's rehearing petition, with no member of the court calling for a vote. Pet. App. 77a-78a, 79a-80a.

REASONS FOR DENYING THE PETITION

The Government asks this Court to review the D.C. Circuit's holding that section 1395hh(a)(2) required notice-and-comment rulemaking on the unique facts presented here. But a decision on that issue would not change the outcome in this case. That is because, in an alternate holding that the Government does not ask this Court to review, the D.C. Circuit found that section 1395hh(a)(4) *independently* required notice and comment due to the failure in prior rulemaking on the same underlying Medicare payment policy. The Government's afterthought that section 1395hh(a)(4) somehow depends on the section 1395hh(a)(2) inquiry does not import that independent holding into the Question Presented, resolution of which would be purely academic.

Even apart from that glaring vehicle problem, there is no circuit split warranting review. No other decision, court of appeals or otherwise, comes close to contradicting the D.C. Circuit's holding that section 1395hh(a)(4) required notice-and-comment rulemaking here. There is also no conflict with the D.C. Circuit's application of the text of section 1395hh(a)(2) to the unusual circumstances here—the only issue the petition presents for review. And because the D.C. Circuit did not decide whether the decision at issue was in fact an interpretive rule, it is far from clear that any distinction drawn between the Medicare Act and the APA would be dispositive in this or any other case. At most, the D.C. Circuit departs in the abstract from other courts of appeals that did not grapple with the marked differences between the Medicare Act and the APA. The D.C. Circuit's thorough and straightforward analysis of section 1395hh(a)(2)'s notice-and-comment requirement yielded a faithful application of the text to the facts here. Other circuits might very well adopt that analysis if presented with a need to engage on the question. For those reasons, this Court's intervention would be premature.

The Government's assertion that the D.C. Circuit's decision impairs its ability to administer the Medicare program is not grounded in reality. Requiring notice-and-comment rulemaking for the unique agency issuance at issue here—the byproduct of years of litigation stemming from the Secretary's perpetual denial of a policy change and significant financial impact on hospitals (which the Government now embraces)—would have little to no impact on the

agency's operations. Indeed, as the Government acknowledges, the D.C. Circuit's opinion addressed a transitional problem: HHS engaged in notice-and-comment rulemaking and issued a new final rule applying to fiscal year 2014 and beyond. And to the extent the government's hypothetical concerns ever materialize in other Medicare contexts, the Court can grant review at that time—in a case where resolution of the question presented would actually matter.

I. REVIEW HERE WOULD BE ACADEMIC IN LIGHT OF THE D.C. CIRCUIT'S INDEPENDENT SECTION 1395hh(a)(4) HOLDING.

1. The D.C. Circuit explicitly found two independent bases for invalidating HHS's decision to include part C days in the Medicare fractions, sections 1395hh(a)(2) and 1395hh(a)(4). "[*E*]*ven if* HHS were correct that the Medicare Act somehow incorporated the APA's notice-and-comment exception for interpretive rules," the Court held, "*HHS would still not prevail here.* That is because another provision of the Medicare Act, Section 1395hh(a)(4), expressly required notice and comment in this case." Pet. App. 17a (emphasis added).

Unlike section 1395hh(a)(2), which mandates notice-and-comment rulemaking for setting and changing a specific category of Medicare standard (*i.e.*, "a substantive legal standard *** governing the *** payment for services"), section 1395hh(a)(4) imposes a notice-and-comment requirement for any "provision" of a certain category of invalidly adopted final regulation (*i.e.*, one "not a logical outgrowth of a

previously published notice of proposed rulemaking"). As the D.C. Circuit explained, "such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation." Pet. App. 17a-18a (citation omitted).

Section 1395hh(a)(4) is tailor-made for this first-of-its-kind case. As the D.C. Circuit reasoned: "HHS's 2004 rule treating Part C enrollees as 'entitled to benefits under Part A' [was vacated] because the 2004 rule 'was not a logical outgrowth of the proposed rule.'" Pet. App. 18a (quoting *Allina I*, 746 F.3d at 1109). Under section 1395hh(a)(4), "HHS therefore had to provide a further opportunity for public comment and a publication of the provision again as a final regulation before [it] could re-impose the rule. HHS did not do so." *Id.* (internal quotation marks and citation omitted). Rejecting HHS's argument that it was excused from notice-and-comment rulemaking because it chose (purportedly) to act through adjudication "rather than rulemaking," the D.C. Circuit found that "[t]he statutory text says that the vacated rule may not 'take effect' at all until there has been notice and comment." *Id.* (quoting section 1395hh(a)(4)).[3]

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[3] The Government revives that merits argument before this Court, asserting that "[a]gency adjudication *** is an established method for resolving interpretive issues" not addressed by regulations. Pet. 22. However true that may be as a general matter under the APA, it ignores section 1395hh(a)(4)'s specific mandate under the Medicare Act in the

2. The Government's Question Presented does not expressly raise the section 1395hh(a)(4) holding or fairly include it. The Government frames the Question Presented as follows:

> "The Department of Health and Human Services (HHS) must utilize notice-and-comment rulemaking to promulgate rules, requirements, or statements of policy that "establish[] or change[]" a "substantive legal standard" governing payment for services under the Medicare Act, 42 U.S.C. 1395hh(a)(2). See 42 U.S.C. 1395hh(b)(1). The question presented is:
>
> Whether Section 1395hh(a)(2) requires HHS to conduct notice-and-comment rulemaking before providing instructions to a Medicare Administrative Contractor that makes initial determinations of payments due under Medicare, when those instructions rest on a non-legally-binding administrative interpretation of a relevant statutory provision.

Pet. (I).

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event of a logical outgrowth failure. Tellingly, the cases on which the Government relies, *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 96 (1995), and *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947), say nothing about section 1395hh(a)(4) or its application to such an invalidly adopted Medicare rule. Nor could they: the 1995 *Guernsey* decision predated the 2003 enactment of section 1395hh(a)(4) by several years, and *Chenery* (not even a Medicare case) predated it by nearly six decades.

The Government plainly has not asked this Court to review the D.C. Circuit's independent section 1395hh(a)(4) holding. The Question Presented does not mention section 1395hh(a)(4) at all. Pet. (I). And the Government does not even address section 1395hh(a)(4) until the bottom of page 21 of its 23-page petition.

When it finally gets around to it, the Government obliquely suggests that section 1395hh(a)(4)'s notice-and-comment requirement somehow depends on section 1395hh(a)(2). Pet. 22-23. That suggestion is both newly minted and utterly unsupported. The Government did not raise any connection between the provisions in merits briefing before the D.C. Circuit. In fact, until it petitioned for rehearing *en banc*, the Government did not respond *at all* to the hospitals' arguments throughout the litigation that HHS's failure to undertake notice-and-comment rulemaking violated section 1395hh(a)(4). Waiver aside, the lack of any decisions from "other courts" on the issue (Pet. 22), *see* pp. 23-24, *infra*, hardly supports the Government's new intimation that the section 1395hh(a)(4) notice-and-comment requirement depends on the application of the separate and distinct section 1395hh(a)(2) requirement.

This Court has explained that a question not directly mentioned in the question presented (as here) must be "anterior" or a predicate to the question presented to be "fairly included" in it. *Ballard v. Commissioner*, 544 U.S. 40, 46-47 & n.2 (2005); *compare Richlin Sec. Serv. Co. v. Chertoff*, 553 U.S. 571, 579 n.4 (2008) ("Since the question

presented cannot genuinely be answered without addressing the subsidiary question, we have no difficulty concluding that the latter question is 'fairly included' within the former. See this Court's Rule 14.1(a).''). The question whether a prior logical outgrowth failure triggers the mandate to engage in additional notice-and-comment rulemaking under section 1395hh(a)(4) is by no means anterior to, or dependent upon, the independent question whether section 1395hh(a)(2) required that notice-and-comment process for a substantive legal standard governing payment. As the D.C. Circuit made clear below, the Government violated section 1395hh(a)(4) "even if" the Medicare Act "somehow incorporated the APA's notice-and-comment exception for interpretive rules." Pet. App. 17a. The mere fact that the two distinct statutory provisions both address notice-and-comment rulemaking is insufficient to establish that a question presented concerning one provision subsumes the other. *See Yee v. City of Escondido*, 503 U.S. 519, 537 (1992).

Any opinion from this Court resolving the Question Presented would thus be advisory as the judgment would stand regardless. This Court reviews judgments, not opinions, *see e.g., Camreta v. Greene*, 563 U.S. 692, 704 (2011), and should deny review on that basis alone.

II. THERE IS NO CIRCUIT SPLIT WARRANTING REVIEW.

A. The D.C. Circuit's Section 1395hh(a)(4) Holding Is One of First Impression

The Government's half-hearted effort to manufacture a circuit conflict with its vague reference to how "other courts" have supposedly ruled on section 1395hh(a)(4) does not withstand any scrutiny. The Government offers that "other courts have not concluded that Section 1395hh(a)(4) *** requires notice-and-comment rulemaking where Section 1395hh would not require such rulemaking for a (non-binding) interpretive action by CMS in the first place." Pet. 22-23. True enough. But as the conspicuous omission of any cases cited to support that statement would suggest, there are no decisions—from any court in any jurisdiction—on that point.

A Westlaw search reveals only six other decisions (two in the prior litigation on part C days) even citing section 1395hh(a)(4) since its enactment in 2003.[4] None comes close to holding, in conflict

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[4] *See Allina I*, 746 F.3d at 1109 (citing section 1395hh(a)(4) for the proposition that "the Medicare statute has no harmless error exception"); *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 267 n.9 (D.D.C. 2015) (citing section 1395hh(a)(4) as supplying an exception to the doctrine permitting an unlawfully promulgated rule to stay in place where equity demands it); *Allina Health Servs. v. Sebelius*, 904 F. Supp. 2d 75, 94 n.13 (D.D.C. 2012) (declining to decide whether section 1395hh(a)(4) automatically requires vacatur for notice-and-comment violation because court had already

with the D.C. Circuit, that section 1395hh(a)(4) permits implementation of a Medicare payment policy change, without further notice and comment, when the change was initially adopted through a rulemaking vacated for a logical outgrowth failure. Not surprisingly, the petition also cites no decisions of "other courts of appeals" for the proposition that the Medicare agency should be able to apply its purportedly "non-binding understanding" of the statute "to adjudicate *** Medicare reimbursement" claims here. *See* Pet. 22-23; p. 34, *infra*. It goes without saying that silence on a particular question of first impression does not create a circuit conflict.

B. There Is No Circuit Split on the Section 1395hh(a)(2) Question Warranting Review.

The undeveloped conflict on the general question whether the Medicare Act incorporates the APA's notice-and-comment exception for interpretive rules does not warrant this Court's review of the specific application of section 1395hh(a)(2) raised here.

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vacated Secretary's action on other grounds), *rev'd in part on other grounds*, 746 F.3d 1102 (D.C. Cir. 2014); *Texas All. for Home Care Servs. v. Sebelius*, 811 F. Supp. 2d 76, 99 n.17 (D.D.C. 2011), *aff'd*, 681 F.3d 402 (D.C. Cir. 2012) (finding no logical outgrowth failure); *National Ass'n for Home Care & Hospice, Inc. v. Sebelius*, No. 08-1765 (RBW), 2009 WL 9057020, *1-2 (D.D.C. Sept. 29, 2009) (dismissing case on jurisdictional grounds without deciding the merits of a challenge under section 1395hh(a)(4)); *Premier Med. Supplies, Inc. v. Leavitt*, No. 1:07cv3809, 2008 WL 11381846, at *5 (N.D. Ohio June 30, 2008) (finding no logical outgrowth failure).

1. The Government's Question Presented is narrow and fact-specific: "Whether Section 1395hh(a)(2) requires HHS to conduct notice-and-comment rulemaking before providing instructions to a Medicare Administrative Contractor that makes initial determinations of payments due under Medicare, when those instructions rest on a non-legally-binding administrative interpretation of a relevant statutory provision." Pet. (I). Intimating a circuit conflict on that fact-bound (and misleading, *see* pp. 33-35, *infra*) question, the Government contends: "As the D.C. Circuit acknowledged, the decisions of other courts of appeals reflect the view that instructions from HHS to its [contractors] about Medicare fractions *** do not qualify as a 'substantive legal standard' under Section 1395hh(a)(2)." Pet. 14. That is flatly incorrect. *None* of the cases on which the Government relies concerned the Medicare fractions, let alone found that the agency was exempt from notice-and-comment rulemaking for the change to include part C days as part-A-entitled days. There is thus no circuit split on the particular question presented here.

The issue on which the D.C. Circuit indicated a departure from other circuits was its "holding that the Medicare Act does not incorporate all of the APA's exceptions to the notice-and-comment requirement." Pet. App. 17a. The D.C. Circuit expressly declined, however, to decide whether the decision to include part C days in the Medicare fractions constituted an APA interpretive rule. *Id.* 15a. Respondents vigorously challenged that characterization in the lower courts, and it is far from

obvious that the APA label fits. *See* Pet. App. 34a-35a; *see also* pp. 27-28, *infra*. Absent a decision from the D.C. Circuit on that question, it is unclear whether that court's application of the plain text of the Medicare Act produces an outcome that is any different than it would reach under the APA on the facts presented in this case. That is not a question for this Court to decide in the first instance. *See, e.g.*, *McLane Co. v. EEOC*, 137 S. Ct. 1159, 1170 (2017) ("[Ours is] a court of [final] review, not of first view.") (internal quotation marks and citation omitted).[5]

2. On the more general interpretive-rule-exception question addressed by the D.C. Circuit, the other circuit decisions the Government cites offer little more than conclusory statements appearing mostly in footnotes and all resting on an unexamined assumption that the Medicare Act incorporates the APA's exceptions. The first cited decision, *Warder v. Shalala*, 149 F.3d 73 (1st Cir. 1998), merely assumed (in a footnote) that the Medicare Act incorporates the

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[5] Review by this Court would also be premature because there are other grounds for invalidating the agency's 2014 action: the Secretary's interpretation is inconsistent with the language and intent of the Medicare DSH statute (*see* note 2, *supra*); the changed standard is arbitrary and capricious for several reasons, including the agency's failure to address the significant economic impact of the change (*see* pp. 36-38, *infra*); under section 1395hh(e)(1)(A), "a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied *** retroactively to items and services furnished before the effective date of the change" except under certain circumstances not relevant here (*see* p. 7, *supra*).

APA's exceptions without actually deciding the question. *See id.* at 79 n.4 ("We proceed herein as if the [statute's] exemption for interpretive rules were identical to the APA's. *** [The plaintiff] has not argued that the two standards are materially different."). The second case, *Erringer v. Thompson*, 371 F.3d 625 (9th Cir. 2004), also did not decide the question, as the court "found no reason to explore the possibility of a distinction between the Medicare Act and the APA." *Id.* at 633. And the third (again in a footnote) incorrectly cited *Erringer* as "[holding] that [section 1395hh(a)(2)] imposes no standards greater than those established by the APA," and stated its agreement on that "corollary" issue. *Baptist Health v. Thompson*, 458 F.3d 768, 776 n.8 (8th Cir. 2006). This is not the sort of mature circuit split reflecting the well-considered analysis of the lower courts that would inform and assist this Court's consideration of the matter.

3. The strength of the D.C. Circuit's thorough and considered decision makes it all the less likely that a mature conflict will ever emerge. The D.C. Circuit's unanimous application of the plain text of section 1395hh(a)(2) to the facts here is faithful to "Congress's use of different language and its establishment of different notice-and-comment requirements in the Medicare Act and the APA." Pet. App. 16. The Government's latest responses to that analysis are unpersuasive and fail to advance the case for review.

Without actually contending that HHS's determination to include part C days in the Medicare fractions constitutes an "interpretive rule"—an issue

the D.C. Circuit declined to reach (Pet. App. 15a)—the Government explains it has "understood" (Pet. 15) that the Medicare Act's special rulemaking requirements contain the APA's express exception for interpretive rules. Pet. 15-18. But, as the D.C. Circuit observed, section 1395hh(a)(2) states: "'*No* rule, requirement or other statement of policy *** shall take effect *unless* it is promulgated' through notice and comment rulemaking." *Id.* 15a-16a (quoting 42 U.S.C. § 1395hh(a)(2)). Section 1395hh(a)(2) imposes APA-independent criteria that trigger notice-and-comment rulemaking, without any carve-out for interpretive rules. Pet. App. 12a. The plain text speaks for itself. *See* p. 15, *supra*.

The context of section 1395hh(a)(2) also undercuts the Government's position. A neighboring provision, section 1395hh(b), expressly incorporates another APA exception to notice and comment—"[s]pecifically, the *** 'good cause' exception." Pet. App. 16a; *see* 42 U.S.C. § 1395hh(b)(2). The inclusion of the good-cause exception shows that Congress did not incorporate the exemption for interpretive rules *sub silencio*. Pet. App. 16a. ("Congress knew how to incorporate the APA's notice-and-comment exceptions into the Medicare Act when it wanted to.").

Section 1395hh(c) (which the Government does not mention) also cuts against its atextual reading. That provision demands periodic publication of a list of "interpretative rules" when those rules "are not published pursuant to subsection (a)(1)," *i.e.*, by notice-and-comment rulemaking. By requiring publication of a list of interpretative rules that have *not* gone through notice and comment as required by

section 1395hh(a)(2), section 1395hh(c) presupposes that some interpretative rules *are* subject to section 1395hh(a)(2)'s notice-and-comment requirement.

Rather than engage on those textual and structural contours, the government focuses on the "legal landscape" at the time Congress enacted the special Medicare rulemaking provisions. From the premise that Congress would have been familiar with the APA's rulemaking standards, the Government reasons that the D.C. Circuit's decision must be incorrect because "[n]othing in Section 1395hh suggests that Congress intended to apply a new notice-and-comment requirement for subsidiary 'interpretive rules,'" Pet. 17, and "[a]n 'interpretive rule' by its nature does not 'establish[] or change[]' a 'substantive legal standard.'" *Id.* 17-18 (citation omitted).[6] Yet the Government fails to offer any reason why Congress adopted particular requirements in the Medicare Act only to restate there what the APA already required.[7]

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[6] As it did below, the Government here ignores the fact that the APA itself uses the term "substantive rule" in a manner showing that "interpretative rules and statements of policy" can be substantive as opposed to procedural. *See* 5 U.S.C. § 553(d) ("The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except— *** interpretative rules and statements of policy.").

[7] Congress first added a notice-and-comment requirement to the Medicare Act in 1986, long after the agency had itself recognized the need to follow the APA. *See* Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9321(e), 100 Stat. 1874, 2017 (1986); 36 Fed. Reg. 2,531-02, 2,532 (Feb. 5, 1971) (Secretary agreeing to "utilize the public participation

Further, the Government's argument gets the analysis backwards. The section 1395hh(a)(2) inquiry does not begin with the question whether the agency's issuance is an "interpretive rule" within the meaning of the APA.[8] Rather, the analysis sensibly starts with the text of section 1395hh(a)(2), which requires notice and comment for any "rule, requirement, or other statement of policy" that "establishes or changes" a "substantive legal standard" governing "payment for services." Pet. App. 12a. By applying the plain meaning of those terms, the D.C. Circuit determined that HHS's decision to include part C days in Medicare fractions met the section 1395hh(a)(2) test for notice-and-comment rulemaking. *Id.*

The Government also contends that, under the D.C. Circuit's rationale, "CMS could not have properly calculated *any* Medicare fractions for *any* hospital after the 1997 enactment of Medicare Part C, *** [because] fulfilling that obligation required the agency to apply *some* interpretation of the Medicare-fraction statute." Pet. 21. That also is incorrect. As

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procedures of the APA" in issuing "rules and regulations relating to *** benefits").

[8] The Government incorrectly invokes *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199 (2015), to claim that the D.C. Circuit erred. *See* Pet. 21 n.12. To the contrary, this Court recognized there that Congress sometimes drafts special provisions to provide additional procedures or protections, beyond what the APA provides, to address when agencies "alter their views." *Perez*, 135 S. Ct. at 1209.

described above, HHS issued a regulation in 1986 requiring that only days covered and paid under part A were to be treated as part-A-entitled. *See* pp. 7-8, *supra*; *see also Catholic Health Initiatives Iowa Corp.*, 718 F.3d at 921 n.5 ("[In the 1986 regulation], the Secretary interpreted the phrase 'entitled to benefits under part A of [Medicare]' in the Medicare fraction to include only 'covered Medicare Part A inpatient days.'") (second alteration in original). HHS could follow its pre-2004 regulation for the years prior to the 2013 prospective rule change without going through notice-and-comment rulemaking.

As the D.C. Circuit found below, "[w]e must respect Congress's use of different language and its establishment of different notice-and-comment requirements in the Medicare Act and the APA." Pet. App. 16a. The Government's claim that section 1395hh(a)(2) should be interpreted to mirror the APA fails entirely to engage on the Medicare Act's distinct language and the facts presented.

In light of the D.C. Circuit's well-reasoned decision, those few courts with limited treatment of the Medicare Act's notice-and-comment rulemaking requirement might well revise their rudimentary positions. As the Government recognized below, Pet. App. 17a n.4, the D.C. Circuit did exactly that. In *Monmouth Medical Center v. Thompson*, 257 F.3d 807 (D.C. Cir. 2001), the court "s[aw] no reason to explore the possibility of a distinction" between the APA and the Medicare Act. *Id.* at 814. When compelled to "explore th[at] possibility," *id.*, however, the D.C. Circuit concluded that there is in fact a distinction between the two statutes. Pet. App. 17a.

If other courts after thorough consideration aligned their decisions with the D.C. Circuit (or, if further percolation revealed that the D.C. Circuit's departure from other courts is merely semantic and not outcome determinative), there would be no conflict for this Court to resolve. But if not, there would at the very least be more fulsome analysis of the matter for future consideration by this Court.

III. THE D.C. CIRCUIT'S DECISION HAS NO IMPACT OF NATIONAL IMPORTANCE WARRANTING REVIEW

A. The Application of the Medicare Act to the Irregular Facts Here Lacks Prospective Importance

The D.C. Circuit's decision in this aberrational litigation on part C days in the DSH payment does not have material future implications for the operation of the Medicare program.

1. As Petitioner acknowledges, Pet. 23 n.13, any potential effect of review in this case would be time-limited. In 2013, the Secretary adopted a new, prospectively effective rule on the exact issue—treatment of part C days in the Medicare fractions—in this litigation. *See id.* at 7-8 n.6; *id.* at 23 n.13; 78 Fed. Reg. at 50,614-15. The dispute here relates only to periods from 2004 to 2013.

2. The D.C. Circuit's decision here, arising in the context of highly irregular agency proceedings, could not reasonably be expected to disrupt normal agency operations. First, denying that the 2004 rule had made a change in the DSH payment standard, the agency tried to apply it retroactively to pre-2004

years—a gambit the D.C. Circuit rejected. *Northeast Hosp.*, 657 F.3d at 13-17. Second, the 2004 rule was not a logical outgrowth of the proposed rule; after the agency initially attempted to apply it to later years in 2009, the D.C. Circuit vacated the rule. *Allina I*, 746 F.3d at 1109.[9]

Meanwhile, the agency in 2013 undertook the new, prospective-only rulemaking discussed above (while still denying the change and impact). 78 Fed. Reg. at 50,614-15. But for years between 2004 and 2013, the agency abruptly scrapped notice and comment altogether—seemingly to save money it never said was at stake until now. Unless the agency intends to make a habit of the unusual procedural maneuvers associated with the part C days policy change, the D.C. Circuit decision should be of little consequence. Indeed, before *Allina I*, no Medicare rule had ever been invalidated for a logical outgrowth failure.

3. The publication of binding fractions reflecting a renewed change in Medicare DSH payment policy also has no bearing on the agency's ordinary use of instructions and manual guidance to its contractors.

The publication of Medicare fractions is not a mere "instruction" to Medicare contractors. The 2012 fractions and the renewed policy they embody are binding on all hospitals when they seek DSH

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[9] The district court in *Allina I* denounced the government's "irregular legal gamesmanship" in denying the policy change after the D.C. Circuit's contrary holding in *Northeast Hospital*. *Allina I*, 904 F. Supp. 2d at 77 n.2.

payments in filing their Medicare cost reports, as well as binding on the agency and its contractors in making payment determinations based on those cost reports. *See* 42 C.F.R. § 412.106(b)(2),(5) (requiring hospitals, the agency, and its contractors to use the agency's published Medicare fraction in calculating DSH payments). The Medicare fractions were also binding on the agency adjudicators in this case. In granting expedited judicial review over the hospitals' challenge here to the fractions and the adoption of the policy reflected in them, the agency's Board found it lacked authority to decide whether those actions "are legal." Pet. App. 57a, 72a.

While attempting to frame them as contractor "instructions," Pet. I, 14, 18, 19, 20, the Government has not actually denied the binding nature of the fractions. Even the petition's Question Presented says only that the fractions "*rest* on a non-legally-binding administrative interpretation of a relevant statutory provision." Pet. I (emphasis added). Elsewhere the petition states that the "agency understanding" of the statute is "non-binding." Pet. 23, not that the issued fractions are non-binding. It is nonsensical to suggest that the "understanding" is non-binding when the fractions themselves are binding on the agency and "hospitals nationwide" as to their Medicare payment determinations. Pet. 8.

The 2014 issuance of the 2012 Medicare fractions is also not a type of manual "guidance" to Medicare contractors for handling, as the Government suggests, "ambiguities that must be resolved" by the contractors in making payment determinations. Pet. 19, 20. The fractions already

reflect the agency's own determination on the binary choice of where to put part C days in the DSH calculation. *See* Pet. 8-9 (Government arguing that the "include[ed] MA [*i.e.*, Part C] Claims Submissions" notation in the 2014 issuance reflected CMS's part C days policy) (alterations in original) (citation omitted); *Allina I*, 746 F.2d at 1108 ("the statute unambiguously requires that Part C days be counted in one fraction or the other"). The 2014 issuance left no "ambiguit[y]" for the contractors to "resolve[]." Pet. 19.

4. The Government is also incorrect, Pet. 20, in suggesting that a notice-and-comment requirement for substantive legal payment standards would be unduly constraining and time consuming. Notice-and-comment rulemaking for Medicare payment standards is already the agency's regular practice, and it takes not a few years as the Government suggests, Pet. 20, but a few months. As explained (pp. 2-3, *supra*), the agency undertakes annual notice-and-comment rulemaking for the inpatient hospital prospective payment system that includes the DSH payment. On average, this annual rulemaking takes 102 days. *See* Add. 1a-3a. The agency has repeatedly used notice-and-comment rulemaking to implement new or revised standards on different categories of patient days in the DSH payment—including at least six rulemakings to determine whether patient days not covered or paid under Medicare part A were to be considered part-A-entitled days and ten other times to make changes to the treatment of other categories of days in the DSH payment. *See* Add. 4a-6a.

Regardless, the D.C. Circuit of course did not conclude that the Medicare Act requires notice-and-comment rulemaking for every agency issuance. It simply applied the text of sections 1395hh(a)(2) and 1395hh(a)(4) to the irregular facts here. The D.C. Circuit does not read its decision in this case to require notice-and-comment rulemaking for non-binding manual instructions that do not "establish the substantive legal standards governing provider reimbursement." *Clarian Health West, LLC v. Hargan*, 878 F.3d 346, 355 (D.C. Cir. 2017) (Medicare manual instructions governing reconciliation of special outlier payments "merely set forth an enforcement policy" and "do not change the legal standards that govern the hospitals *** or the agency.").

B. The Government's New Claim of Financial Impact Undercuts the Petition

The petition is only undermined by the Government's entirely new, unsupported complaint about the financial impact of the underlying issue in this case. Pet. 14, 23. The failure to contend with the impact on hospitals—an important factor the agency must consider as part of any reasoned decision-making—has been among the failures at the core of this entire litigation from the outset. Until now, the agency has never acknowledged—much less rationally considered—in any rulemaking or adjudicatory decision any significant impact of putting the part C days in one DSH fraction versus the other.

In the 2004 final rule the D.C. Circuit vacated in *Allina I*, the agency predicted that the same policy change, even in combination with three other changes expected to reduce the DSH payment, would not "have a significant impact on payments[] [b]ased on an analysis from our actuarial staff." 69 Fed. Reg. at 49,770 (estimating a combined impact for several changes of $50 million). And, as put by the Government in briefing before the D.C. Circuit in this case just last year, "both the 2013 Final Rule and the Administrator's *Allina I* [remand] decision *** refute plaintiffs' concerns about the financial impact of including Part C days in the Medicare/SSI fraction." *See* Gov't C.A. Br. 51. If the impact was not important enough for the agency to recognize in its prior decision-making, *cf. Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (reasoned decision-making requires agency "to consider an important aspect of the problem"), then it hardly constitutes a matter of national importance warranting this Court's review.

In any event, the Government's purportedly new insight as to the financial impact wrought by the policy change only highlights why Congress enacted legislation imposing Medicare-specific notice-and-comment rulemaking requirements. When enacting section 1395hh(a)(2), Congress was concerned in the Medicare context about "important policies being developed without benefit of the public notice and comment period." H.R. Rep. No. 100-391(I), at 430. Because the Medicare program makes $120 billion in expenditures each year just for inpatient hospital services and $675 billion in total, *see*

https://www.cms.gov/fastfacts/, even seemingly small changes in payment standards yield significant changes in reimbursement for hospitals, *see County of Los Angeles v. Shalala*, 192 F.3d 1005, 1010 (D.C. Cir. 1999) ("Given the enormity of the Medicare program, *** seemingly modest percentage differences represent substantial sums of money."). Notice and opportunity for comment are critically important for determining and meaningfully considering the true impact of any payment policy change on hospitals making hard decisions with limited budgets about services, staffing, and other expenditures necessary to meet the health care needs of their communities, including those who lack the means to pay for their care.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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June 19, 2018

ADDENDUM

ADDENDUM

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Appendix 1 – Annual Inpatient Prospective Payment System Rulemakings (Federal Fiscal Years 2003-2018)

FFY	Proposed Rule	Final Rule	Number of Days
2003	67 Fed. Reg. 31,404 (May 9, 2002)	67 Fed. Reg. 49,982 (Aug. 1, 2002)	84
2004	68 Fed. Reg. 27,154 (May 19, 2003)	68 Fed. Reg. 45,346 (Aug. 1, 2003)	74
2005	69 Fed. Reg. 28,196 (May 18, 2004)	69 Fed. Reg. 48,916 (Aug. 11, 2004)	85
2006	70 Fed. Reg. 23,306 (May 4, 2005)	70 Fed. Reg. 47,278 (Aug. 12, 2005)	100
2007	71 Fed. Reg. 23,996 (Apr. 25, 2006)	71 Fed. Reg. 47,870 (Aug. 18, 2006)	115
2008	72 Fed. Reg. 24,680 (May 3, 2007)	72 Fed. Reg. 47,130 (Aug. 22, 2007)	111

FFY	Proposed Rule	Final Rule	Number of Days
2009	73 Fed. Reg. 23,528 (Apr. 30, 2008)	73 Fed. Reg. 48,434 (Aug. 19, 2008)	111
2010	74 Fed. Reg. 24,080 (May 22, 2009)	74 Fed. Reg. 43,754 (Aug. 27, 2009)	97
2011	75 Fed. Reg. 23,852 (May 4, 2010)	75 Fed. Reg. 50,042 (Aug. 16, 2010)	104
2012	76 Fed. Reg. 25,788 (May 5, 2011)	76 Fed. Reg. 51,476 (Aug. 18, 2011)	105
2013	77 Fed. Reg. 27,870 (May 11, 2012)	77 Fed. Reg. 53,258 (Aug. 31, 2012)	112
2014	78 Fed. Reg. 27,486 (May 10, 2013)	78 Fed. Reg. 50,496 (Aug. 19, 2013)	101
2015	79 Fed. Reg. 27,978 (May 15, 2014)	79 Fed. Reg. 49,854 (Aug. 22, 2014)	99
2016	80 Fed. Reg. 24,324 (Apr. 30, 2015)	80 Fed. Reg. 49,326 (Aug. 17, 2015)	109

FFY	Proposed Rule	Final Rule	Number of Days
2017	81 Fed. Reg. 24,946 (Apr. 27, 2016)	81 Fed. Reg. 56,762 (Aug. 22, 2016)	117
2018	82 Fed. Reg. 19,796 (Apr. 28, 2017)	82 Fed. Reg. 37,990 (Aug. 14, 2017)	108
		Average	**102**

Appendix 2 – Notice and Comment Rulemaking on Medicare Part A-Entitled Patient Days in DSH Calculation

Rule Change	Final Rule
Adopting a requirement that days must be covered and paid under part A to be included as part-A-entitled	51 Fed. Reg. 16,772, 16,777 (May 6, 1986)
Attempting to change 1986 rule through rule later vacated in *Allina I*	69 Fed. Reg. 48,916, 49,098-99 (Aug. 11, 2004)
Addressing "days for which Medicare was not the primary payer"	70 Fed. Reg. 47,278, 47,441 (Aug. 12, 2005)
Implementing additional changes to the regulation's text consistent with the 2004 rule	72 Fed. Reg. 47,130, 47,384 (Aug. 22, 2007)
Further amending the regulation text with respect to part C days	75 Fed. Reg. 50,042, 50,285 (Aug. 16, 2010)
Prospectively reinstating the 2004 rule vacated in *Allina I*	78 Fed. Reg. 50,496, 50,614 (Aug. 19, 2013)

Appendix 3 – Notice and Comment Rulemaking on Categories of Patient Days in DSH Calculation Other than Medicare Part A-Entitled

Rule Change	Final Rule
Days for patients who were eligible for Medicaid but for which Medicaid did not make payment	63 Fed. Reg. 40,954, 40,985 (July 31, 1998)
Days for patients eligible for Medicaid expansion waiver programs	65 Fed. Reg. 3,136, 3,136-39 (Jan. 20, 2000)
Patient days in units or wards providing services generally payable under part A	68 Fed. Reg. 45,346, 45,416-18 (Aug. 1, 2003)
Outpatient observation days and patient days in swing beds used to provide skilled nursing services	68 Fed. Reg. 45,346, 45,418-19 (Aug. 1, 2003)
Patient days in labor/delivery rooms	68 Fed. Reg. 45,346, 45,419-20 (Aug. 1, 2003)

Rule Change	Final Rule
Days for patients with limited benefits under Medicaid expansion waivers	68 Fed. Reg. 45,346, 45,420-21 (Aug. 1, 2003)
Outpatient observation days for patients ultimately admitted as an inpatients	69 Fed. Reg. 48,916, 49,096-98 (Aug. 11, 2004)
Labor/delivery room patient days	74 Fed. Reg. 43,754, 43,899-901 (Aug. 27, 2009)
Outpatient observation days	74 Fed. Reg. 43,754, 43,905-08 (Aug. 27, 2009)
SSI-entitled days for the Medicare fraction	75 Fed. Reg. 50,042, 50,275-86 (Aug. 16, 2010)

No. 17-1484

In the Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

Respondents argue that the D.C. Circuit's interpretation of Section 1395hh's notice-and-comment rulemaking provisions does not warrant further review for two reasons: first, they contend that the factual context here narrows the panel's holding; and, second, they contend that the decision below independently rests on a holding about Section 1395hh(a)(4) that the government has not properly challenged. Both contentions are flawed.

1. a. The D.C. Circuit created a conflict warranting review by holding that Section 1395hh's notice-and-comment procedures apply to interpretive rules. Pet. 14-15. The D.C. Circuit itself stated that it "respectfully disagree[d]" and was "breaking with several other courts of appeals." Pet. App. 17a.

Respondents do not deny that acknowledged conflict. They instead assert (Br. in Opp. (Br.) 24-25) that the conflict is "undeveloped" and "does not warrant" review in the "specific" context here involving "Medicare

fractions." But the acknowledged conflict over the application of Section 1395hh's notice-and-comment requirements to interpretive rules is not diminished because other circuits have addressed interpretive materials not involving Medicare fractions. The D.C. Circuit found it dispositive that agency contractors are required to follow agency instructions when making *initial* reimbursement decisions—even though those instructions are not binding on administrative review—and that those instructions change (or establish) a practice affecting Medicare payments. Pet. App. 12a-14a. Nothing in those holdings turns on any fact-bound feature of Medicare fractions. Nor is it significant that the D.C. Circuit declined to decide whether the agency's interpretation embodied in its Medicare-fraction calculations "constituted an APA interpretive rule." Br. 25. The D.C. Circuit assumed the question *arguendo* by ruling against the government on the ground that, even if the fractions constituted an interpretive rule, they would still require notice-and-comment rulemaking. Pet. App. 15a; see *id.* at 12a-14a. That holding was dispositive below and warrants review.

Respondents contend (Br. 26-27) that the circuit conflict is not "mature." But they do not deny that the conflicting holdings of other courts of appeals would bind future panels of those courts. Respondents, for instance, note that the Ninth Circuit in *Erringer* v. *Thompson*, 371 F.3d 625, 633 (2004), stated that it did not have to address the "possibility" that the Medicare Act might draw "the line between substantive and interpretive rules in a different place than the APA" because the interpretive rule at issue was "not close" to the line. But that statement does not alter *Erringer*'s holding that

Section 1395hh does not require notice-and-comment rulemaking for interpretive rules. *Ibid.*; see Pet. 14-15.

Furthermore, review is particularly warranted here because universal venue for providers' Medicare actions lies in the D.C. Circuit. Pet. 23. Respondents offer no relevant response. The monetary stakes and hospitals' legal sophistication will likely lead to future cases raising similar issues being litigated in the District of Columbia, where the decision below constitutes binding precedent. Indeed, after the decision below, providers filed about 30 similar Medicare cases in the District of Columbia, most of which have been stayed pending the disposition of this petition.

b. Certiorari is also warranted because the D.C. Circuit's interpretation of Section 1395hh's rulemaking provisions, if applied to the entire Medicare program, would impair the government's ability to administer its reimbursement process. Requiring the agency to conduct notice-and-comment rulemaking before it can establish or modify provisions of the Provider Reimbursement Manual (PRM) and other interpretive materials that Medicare contractors must follow would make it much more difficult for HHS to administer the Medicare program. Pet. 19-20.

Respondents contend (Br. 32-36) that the D.C. Circuit's decision concerning the particular Medicare fraction dispute here does not have prospective significance given the separate notice-and-comment rule effective FY2014. Even for the period from FY2005 to FY2013, however, the Medicare-fraction issue alone governs $3 to $4 billion in funding. Pet. 23 & n.13.[1] In any event,

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[1] Respondents do not dispute the accuracy of the estimate. About 2700 hospitals obtain DSH payments, and respondents' claim

respondents do not deny that, under the decision below, PRM provisions and other interpretive guidance addressing payment issues not directly controlled by statute or notice-and-comment regulations would constitute "requirements" establishing or changing "substantive legal standards" and require notice-and-comment rulemaking. Indeed, a mere three days after that decision, respondents' counsel argued that "cost report instructions" in the PRM interpreting regulatory requirements could not be properly followed, because, under the D.C. Circuit's binding precedent in this case, they constitute "requirement[s]" modifying Medicare standards that must be promulgated through Section 1395hh notice-and-comment rulemaking, which has no exception for "interpretive rules." Pl. Summ. J. Mem. at 30 & n.4, *Rocky Mountain Health Maint. Org., Inc.* v. *Price*, No. 17-cv-242 (D.D.C. July 28, 2017); see Pl. Opp. to Gov't Mot. for Summ. J. at 19-20, *Rocky Mountain*, *supra* (Nov. 1, 2017); see also, *e.g.*, Pls. Summ. J. Mem. at 24-26, *HealthAlliance Hosps., Inc.* v. *Wright*, No. 17-cv-917 (D.D.C. Oct. 2, 2017) (similar rulemaking argument by respondents' counsel).[2]

In illustrating the practical difficulties posed by the decision below, the petition explains that if the court of appeals were correct that the agency's calculation of FY2012 Medicare fractions (counting Part C days) "change[d] a substantive legal standard," then the

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$48.5 million in additional reimbursement for just nine hospitals for one year. Pet. App. 59a-61a.

[2] Respondents suggest (Br. 2-3, 35) that notice-and-comment rulemaking is not a significant hurdle because Congress requires it in certain Medicare contexts. That disregards the much broader scope of rulemaking that would be required for all interpretive guidance under the logic of the decision below.

agency's earlier calculation of such fractions (omitting Part C days) must have also "established" the standard in the first instance, 42 U.S.C. 1395hh(a)(2), such that notice-and-comment rulemaking was required before either practice could be followed. Pet. 20-21. The agency thus could not have calculated any Medicare fractions after the 1997 enactment of Medicare Part C without notice-and-comment rulemaking, notwithstanding the obvious need to discharge its obligation to calculate those fractions annually to administer Medicare's reimbursement regime and notwithstanding that providers may challenge those fractions, which—like other initial cost-reporting determinations—are not binding on administrative or judicial review. *Ibid.*; see pp. 6-7, *infra*.

Respondents deny that result by arguing (Br. 7-8, 30-31) that 42 C.F.R. 412.106(b)(2)(i) (2003) had already established the "substantive legal standard" by "unambiguously exclud[ing]" Medicare Part C days. Respondents miss the point and are wrong. They miss the point because the logic of the decision below would apply to any context in which the agency gives its contractors interpretive instructions about making initial reimbursement decisions. They are wrong because, as the D.C. Circuit has determined, "[p]rior to 2004, the regulation did not specify where [Part C] enrollees should be counted." *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 14 (2011); cf. Pet. 7-8.[3] And because the regulation

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[3] The regulation included in the Medicare fraction "the number of covered patient days" "furnished to *patients* who * * * were entitled to both Medicare Part A and SSI." 42 C.F.R. 412.106(b)(2)(i) (2003) (emphasis added). Because Part C patients must be "entitled to benefits under [P]art A," 42 U.S.C. 1395w-21(a)(3)(A), it was at least ambiguous whether Section 412.106(b)(2)(i) was properly interpreted as counting Part C days in that fraction. See Pet. 4-5.

did not unambiguously resolve the issue, the agency's initial calculations—under the panel's reasoning—would have "established" a substantive legal standard requiring notice-and-comment rulemaking whether they included or excluded Part C days. That result and the prospect of its application across the Medicare program underscore the need for review.

c. Respondents offer little response to the petition's arguments that the statutory term "substantive legal standard" limits Section 1395hh(a)(2) to substantive (not interpretive) rules imposing legal standards that bind the agency on administrative review, see Pet. 15-18; and that the term "requirements" is limited to provisions that bind not only Medicare contractors, but also the agency itself on review, see Pet. 18-19.

Instead, respondents rest on arguments that were largely not addressed or relied upon by the court of appeals. For instance, respondents erroneously assert (Br. 33-34) that the Medicare fractions *are* "binding" on review. Respondents cite a regulation that merely instructs *contractors* making *initial* determinations to "add[]" a CMS-calculated Medicare fraction to their own calculations, 42 C.F.R. 412.106(b)(2) and (5). But if the provider seeks agency review, the fraction (like the rest of the initial decision) has no binding force. Pet. 5-6. Thus, contrary to respondents' suggestion (Br. 34), the D.C. Circuit held that the PRRB correctly declined to address the fractions here not because they were themselves binding on the PRRB, but because respondents *argued* that the "fractions constituted a new regulation" that was "procedurally [in]valid" and that the PRRB lacked authority to decide that question. Pet. App. 11a.

Respondents rely (Br. 28) on Section 1395hh(b)(2)'s express incorporation of the APA's good-cause provision

(5 U.S.C. 552(b)(B)) and the absence of an interpretive-rule exemption like that in 5 U.S.C. 552(b)(A). But the APA's notice-and-comment requirement is worded generally, applying to all "rules," so an express exemption for "interpretative" rules was necessary. In Section 1395hh, in contrast, the term "substantive legal standard" itself excludes interpretive rules. Pet. 15-18. Moreover, when Congress enacted Section 1395hh(b)'s cross-reference to the APA's good-cause exception, the Conference Report emphasized that the notice-and-comment provisions would not apply to "interpretive rules." H.R. Conf. Rep. No. 1012, 99th Cong., 2d Sess. 311 (1986).

Respondents note (Br. 29 n.7) that HHS's predecessor agency chose in 1971 to voluntarily "follow the APA['s]" rulemaking requirements, even though the APA itself exempted Medicare's "benefits" program from them, 5 U.S.C. 553(a)(2). See *Humana of S.C., Inc.* v. *Califano*, 590 F.2d 1070, 1082, 1084 & n.103 (D.C. Cir. 1978). Respondents suggest (Br. 29) that there is no "reason why Congress [would have] adopted particular requirements in [Section 1395hh] only to restate there what the APA already required." Respondents are wrong. Congress enacted Section 1395hh's rulemaking requirements because of concerns that HHS would abandon that practice.

In 1982, in a proposed rulemaking, HHS stated that although it "ordinarily" would "use notice and comment procedures" for "Medicare," "even though such action is not required by the [APA]," its "voluntary" policy did not "create any right or benefit enforceable at law," and it would *not* use APA rulemaking where it deemed the costs to "outweigh" the benefits. 47 Fed. Reg. 26,860, 26,860-26,861 (June 22, 1982) (proposing 45 C.F.R. 2.2(c)). In response, a "broad-based coalition" recommended

that Congress require HHS "to follow the procedures delineated in the APA (including notice of proposed rulemaking) when issuing any regulation or rule relating to Medicare." *Medicare Appeals Provisions: Hearing on S. 1158 Before the Subcomm. on Health of the Senate Comm. on Finance*, 99th Cong., 1st Sess. 25-26 (1985). In light of HHS's "proposed regulation," numerous stakeholders told Congress that "the time ha[d] come to make it clear, *by statute*, that Medicare regulations * * * should be subject to the [APA]." *Id.* at 62; see *id.* at 119-120 & n.14, 149, 211, 239-240. That was deemed necessary because of the perception that HHS had "abandoned" its prior "voluntary commitment to subject Medicare to the APA." *E.g.*, *Examination of Quality Care Under Medicare's Prospective Payment System: Hearing Before the Senate Comm. on Finance*, 99th Cong., 2d Sess. 346-347 (1986).

Respondents erroneously rely (Br. 5-6, 37) on a House Report that accompanied different and broader statutory text, see H.R. Rep. No. 391, 100th Cong., 1st Sess. 430, 594-595 (1987), that Congress later rejected by limiting Section 1395hh(a)(2) "only" to matters establishing or changing a relevant "substantive legal standard." H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. 566 (1987); see *id.* at 82. That change was designed to "reflect[] recent court rulings," *id.* at 566, and the only extant rulings at that time were those applying the *APA*'s requirements. Thus, in *American Hospital Ass'n* v. *Bowen*, 834 F.2d 1037, 1045, 1055-1057 & n.4 (1987), the D.C. Circuit held that although notice-and-comment rulemaking was necessary for "substantive rule[s]" having legal force, it was not necessary for "in-

terpretive rules" binding on private contractors assisting HHS in the administration of the Medicare program, because they did not change "substantive standards."

2. Respondents argue (Br. 18-22) that certiorari is unwarranted because the D.C. Circuit also based its decision on Section 1395hh(a)(4). That contention lacks merit. As discussed below, the D.C. Circuit did not rely on Section 1395hh(a)(4) as an independent basis for the decision below, because it applies only to a "regulation" governed by Section 1395hh(a)(2).

a. If an agency's "notice and comment" process is defective because a final rule is not a logical outgrowth of the proposal and if equity requires it, the "unlawfully promulgated regulation" ordinarily "can be left in place while the agency provides the proper procedural remedy." *Fertilizer Inst.* v. *EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991). As respondents acknowledge, Section 1395hh(a)(4) "suppl[ies] an exception to th[at] doctrine, Br. 23 n.4, by prohibiting such a "regulation" from "tak[ing] effect" pending the agency's resolution of the procedural defect, 42 U.S.C. 1395hh(a)(4).

A "regulation" under Section 1395hh(a)(4) is the same type of "regulation" that Section 1395hh(a)(2) earlier defines as a rule, requirement, or statement of policy that establishes or changes a relevant "substantive legal standard." Section 1395hh(a)(4)'s no-effect provision, which is triggered only when a prior notice-and-comment process is deemed defective, logically applies only if the "regulation" in question is itself a binding "regulation" for which Section 1395hh(a)(2) required notice-and-comment rulemaking in the first instance. Indeed, where, as here, an agency applies a non-binding interpretation to facilitate an initial Medicare determi-

nation, no earlier "regulation" has "take[n] effect" because, if it had, the regulation would have also been *binding* on administrative review. Thus, because Section 1395hh(a)(2)'s application to "substantive legal standards" does not apply to agency interpretive provisions, Pet. 15-17, the certiorari petition explains that Section 1395hh(a)(4) does not apply "where Section 1395hh would not [have] require[d] such rulemaking for a (non-binding) interpretive action by CMS in the first place." Pet. 22.

Respondents counter (Br. 18) that the court of appeals' Section 1395hh(a)(4) holding was independent of its Section 1395hh(a)(2) holding merely because the court stated that HHS would not prevail "even if [it] were correct that the [latter] somehow incorporated the APA's notice-and-comment exception for interpretive rules." Pet. App. 17a-18a. The court, however, treated the argument that Section 1395hh "incorporate[s] the APA's interpretive-rule exception" in 5 U.S.C. 553(b)(A), see Pet. App. 15a-16a, as *distinct* from the argument that the non-binding interpretation here is not a "requirement" changing a "substantive legal standard" that would constitute a "regulation" under Section 1395hh(a)(2), *id.* at 12a-14a. Thus, while the court said that its Section 1395hh(a)(4) holding would apply if Section 1395hh incorporated the APA's separate exception for interpretive rules, it did *not* say that Section 1395hh(a)(4) would apply even if the challenged Medicare interpretation is not a "regulation" covered by Section 1395hh(a)(2). To the contrary, the court reasoned that Section 1395hh(a)(4) applied *precisely because* it thought the agency was making the "regulation" that was previously vacated "legally operative," *id.* at 18a, which obviously would not be true if the agency interpretation was not a "rule"

or "requirement" governed by Section 13955hh(a)(2). Reversal of the Section 1395hh(a)(2) holding would thus logically compel reversal of the Section 1395hh(a)(4) holding.

b. Respondents argue (Br. 20-21) that the government's question presented does not encompass the D.C. Circuit's Section 1395hh(a)(4) holding, because that question refers to Section 1395hh(a)(2). But for the reasons above, the Section 1395hh(a)(4) holding rests upon the court's interpretation of Section 1395hh(a)(2) and thus is "fairly included" by the question presented challenging that interpretation. Sup. Ct. R. 14.1(a). In any event, this is not a case where the certiorari petition fails adequately to identify an issue it seeks to bring before the Court. Respondents fully understood and addressed our argument (Pet. 22) concerning Section 1395hh(a)(4). Thus, if this Court were to conclude that the question presented could be clarified by also explicitly referring to Section 1395hh(a)(4), it would be appropriate for the Court to do so in the course of granting review of the question concerning the D.C. Circuit's interpretation of Section 1395hh as requiring notice-and-comment rulemaking. That interpretation warrants this Court's review.

* * * * *

For the foregoing reasons and those stated in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted.

NOEL J. FRANCISCO
Solicitor General

JULY 2018

No. 17-1484

In the Supreme Court of the United States

ALEX M. AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

JOINT APPENDIX

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PETITION FOR A WRIT OF CERTIORARI FILED: APR. 27, 2018
CERTIORARI GRANTED: SEPT. 27, 2018

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Docket No. 16-5255

ALLINA HEALTH SERVICES, DOING BUSINESS AS UNITED HOSPITAL, DOING BUSINESS AS UNITY HOSPITAL, DOING BUSINESS AS ABBOTT NORTHWESTERN HOSPITAL, ET AL., PLAINTIFFS-APPELLANTS

v.

SYLVIA MATTHEWS BURWELL, ET AL., DEFENDANTS-APPELLEES

DOCKET ENTRIES

DATE	PROCEEDINGS
	* * * * *
1/23/17	APPELLANT BRIEF [1656971] filed by All Plaintiffs [Service Date: 01/23/2017] Length of Brief: 12,933. [16-5255] (Webster, Stephanie) [Entered: 01/23/2017 07:08 PM]
2/22/17	APPELLEE BRIEF [1662579] filed by Dr. Thomas E. Price [Service Date: 02/22/2017] Length of Brief: 12,844 Words. [16-5255] (Marcus, Stephanie) [Entered: 02/22/2017 06:09 PM]
	* * * * *
3/22/17	APPELLANT REPLY BRIEF [1667327] filed by All Plaintiffs [Service Date: 03/22/2017] Length of Brief: 6,484 words [16-5255]

DATE	PROCEEDINGS
	(Webster, Stephanie) [Entered: 03/22/2017 03:19 PM]
3/28/17	*JOINT* APPENDIX [1668188] filed by All Plaintiffs. [Volumes: 1] [Service Date: 03/28/2017] [16-5255] (Webster, Stephanie) [Entered: 03/28/2017 01:56 PM]
4/7/17	APPELLANT FINAL BRIEF [1670116] filed by All Plaintiffs [Service Date: 04/07/2017] Length of Brief: 12,942 Words [16-5255] (Webster, Stephanie) [Entered: 04/07/2017 01:39 PM]
4/7/17	APPELLANT FINAL REPLY BRIEF [1670121] filed by All Plaintiffs [Service Date: 04/07/2017] Length of Brief: 6,488 Words [16-5255] (Webster, Stephanie) [Entered: 04/07/2017 01:41 PM]
4/11/17	APPELLEE FINAL BRIEF [1670574] filed by Dr. Thomas E. Price [Service Date: 04/11/2017] Length of Brief: 12,857 Words. [16-5255] (Marcus, Stephanie) [Entered: 04/11/2017 02:34 PM]
	* * * * *
5/11/17	ORAL ARGUMENT HELD before Judges Henderson, Kavanaugh and Millett [16-5255] [Entered: 05/11/2017 11:19 AM]
	* * * * *
7/25/17	PER CURIAM JUDGMENT [1685629] filed that the judgment of the District Court appealed from in this cause is hereby reversed

DATE	PROCEEDINGS
	and the case is remanded for further proceedings, for the reasons in the accompanying opinion. Before Judges: Henderson, Kavanaugh, and Millett [16-5255] [Entered: 07/25/2017 09:56 AM]
7/25/17	OPINION [1685630] filed (Pages: 18) for the Court by Judge Kavanaugh. [16-5255] [Entered: 07/25/2017 09:58 AM]
	* * * * *
10/4/17	PETITION [1696995] for rehearing, for rehearing en banc filed by Appellee Dr. Thomas E. Price [Service Date: 10/04/2017 by CM/ECF NDA] Length Certification: 3,896 Words. [16-5255] (Marcus, Stephanie) [Entered: 10/04/2017 10:32 PM]
	* * * * *
11/3/17	RESPONSE [1703084] to petition for rehearing [1696995-2], petition for rehearing en banc [1696995-3] filed by All Plaintiffs [Service Date: 11/03/2017 by CM/ECF NDA] Length Certification: 3,741 words. [16-5255] (Webster, Stephanie) [Entered: 11/03/2017 08:41 PM]
11/29/17	PER CURIAM ORDER [1706551] filed denying appellee's petition for rehearing [1696995-2]. Before Judges: Henderson, Kavanaugh and Millett. [16-5255] [Entered: 11/29/2017 12:54 PM]

DATE	PROCEEDINGS
11/29/17	PER CURIAM ORDER, En Banc, [1706554] filed denying appellee's petition for rehearing en banc [1696995-3] Before Judges: Garland, Henderson, Rogers, Tatel, Griffith, Kavanaugh, Srinivasan, Millett, Pillard, and Wilkins. [16-5255] [Entered: 11/29/2017 12:56 PM]
12/14/17	MANDATE ISSUED to Clerk, U.S. District Court. [16-5255] [Entered: 12/14/2017 12:47 PM]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Docket No. 1:14-cv-01415-TJK
ALLINA HEALTH SERVICES, ET AL., PLAINTIFFS

v.

SYLVIA MATHEWS BURWELL, DEFENDANT

DOCKET ENTRIES

DATE	DOCKET NUMBER	PROCEEDINGS
8/19/14	1	COMPLAINT against SLIVVIA BURWELL (Filing fee $400 receipt number 0090-3813427) filed by ALLINA HEALTH SERVICES, FLORIDA HEALTH SCIENCES CENTER, INC., MONTEFIORE MEDICAL CENTER, NEW YORK HOSPITAL MEDICAL CENTER OF QUEENS, NEW YORK AND PRESBYTERIAN HOSPITAL MOUNT SINAI MEDICAL CENTER OF FLORIDA, INC., NEW YORK METHODIST HOSPITAL. (Attachments: #1 Civil Cover Sheet, #2 Summons, #3 Summons, #4 Summons) (Webster,

DATE	DOCKET NUMBER	PROCEEDINGS
		Stephanie) (Entered: 08/19/2014)
		* * * * *
9/29/14	8	MOTION for Summary Judgment by ALL PLAINTIFFS (Attachments: #1 Text of Proposed Order) (pursuant to MINUTE ORDER filed 09/29/20147) (rdj) (Entered: 09/30/2014)
10/9/14	9	MEMORANDUM re 8 MOTION for Summary Judgment filed by ALL PLAINTIFFS by ALL PLAINTIFFS. (Attachments: #1 Exhibit A, #2 Certificate of Service) (Webster, Stephanie) (Entered: 10/09/2014)
		* * * * *
11/12/15	24	ANSWER to Complaint by SYLVIA M. BURWELL. (Freeny, Kyle) (Entered: 11/12/2015)
		* * * * *
12/15/15	28	Memorandum in opposition to re 8 MOTION for Summary Judgment filed by SYLVIA M. BURWELL. (Attachments: #1 Certificate of Administra-

DATE	DOCKET NUMBER	PROCEEDINGS
		tive Record Contents, #2 Administrator's Decision on Remand in Allina I, #3 Declaration Declaration of Ing Jye Cheng) (Kennedy, Brian) (Entered: 12/15/2015)
12/15/15	29	MOTION for Summary Judgment by SYLVIA M. BURWELL (Attachments: #1 Memorandum in Support, #2 Certification of Contents of Administrative Record, #3 Declaration Declaration of Ing Jye Cheng, #4 Administrator's Decision on Remand in Allina I, #5 Text of Proposed Order) (Kennedy, Brian) (Entered: 12/15/2015)
1/14/16	30	RESPONSE re 29 MOTION for Summary Judgment filed by ALLINA HEALTH SERVICES, FLORIDA HEALTH SCIENCES CENTER, INC., MONTEFIORE MEDICAL CENTER, MOUNT SINAI MEDICAL CENTER OF FLORIDA, INC., NEW YORK AND PRESBYTERIAN HOSPITAL, NEW YORK HOSPITAL MEDICAL CENTER OF QUEENS, NEW YORK

DATE	DOCKET NUMBER	PROCEEDINGS
		METHODIST HOSPITAL. (Attachments: #1 Exhibit B, #2 Exhibit C) (Webster, Stephanie) (Entered: 01/14/2016)
1/14/16	31	REPLY to opposition to motion re 8 MOTION for Summary Judgment filed by ALLINA HEALTH SERVICES, FLORIDA HEALTH SCIENCES CENTER, INC., MONTEFIORE MEDICAL CENTER, MOUNT SINAI MEDICAL CENTER OF FLORIDA, INC., NEW YORK AND PRESBYTERIAN HOSPITAL, NEW YORK HOSPITAL MEDICAL CENTER OF QUEENS, NEW YORK METHODIST HOSPITAL (Attachments: #1 Exhibit B, #2 Exhibit C) (Webster, Stephanie) (Entered: 01/14/2016)
		* * * * *
2/4/16	33	REPLY to opposition to motion re 29 MOTION for Summary Judgment filed by SYLIA M. BURWELL (Kennedy, Brian) (Entered: 02/04/2016)
		* * * * *

DATE	DOCKET NUMBER	PROCEEDINGS
8/17/16	38	ORDER granting 29 Defendant's Motion for Summary Judgment and denying 8 Plaintiffs' Motion for Summary Judgment. Signed by Judge Gladys Kessler on 08/17/16. (CL) (Entered: 08/17/2016)
8/17/16	39	MEMORANDUM OPINION to the Order denying Plaintiffs' Motion for Summary Judgment and granting Defendant's Motion for Summary Judgment. Signed by Judge Gladys Kessler on 08/17/16. (CL) (Entered: 08/17/2016)
8/26/16	40	NOTICE OF APPEAL TO DC CIRCUIT COURT as to 38 Order on Motion for Summary Judgment 39 Memorandum & Opinion by ALL PLAINTIFFS. Filing fee $505, receipt number 0090-4652772. Fee Status: Fee Paid. Parties have been notified. (Webster, Stephanie) (Entered: 08/26/2016)

DEPARTMENT OF HEALTH
& HUMAN SERVICES

Health Care
Financing Administration

Memorandum

Mar. 13, 2000

FROM : Director
Financial Services Group, OFM

Deputy Director
Medicare Contractor Management, CBS

SUBJECT : Questions and Answers Related to Program Memorandum A-99-62

TO : All Medicare Fiscal Intermediaries

Attached are the questions and answers related to the Program Memorandum to Intermediaries A-99-62 which were either presented at the January 13, 2000 teleconference or subsequently sent to Mr. Chuck Booth.

If there are additional questions based on actual situations, please E-Mail them to CBooth@HCFA.gov.

/s/ CHARLES R. BOOTH
CHARLES R. BOOTH
Director
Financial Services Group
Office of Financial Management

/s/ GERALDINE NICHOLSON for
MARJORIE KANOF, M.D.
Deputy Director
Medicare Contractor Management
Center for Beneficiary Services

Attachment

cc:
All Regional Administrators

QUESTIONS AND ANSWERS
RELATED TO PROGRAM MEMORANDUM INTERMEDIARIES A-99-62
(Referred to as PM A-99-62)

Q1. If an intermediary accepted remittance advices as documentation for the out-of-State Medicaid days in the past, what will the intermediary be required to do to verify the "excluded days" as defined in PM A-99-62 for cost reporting periods beginning on or after January 1, 2000?

A. HCFA will update the Hospital and Skilled Nursing Facility Audit Program to give intermediaries guidance on what procedures to use when auditing the Medicaid days used in the computation of the Medicare DSH payments.

Also, a copy of PM A-99-62 was transmitted to all the State Medicaid Agencies directing them to review this transmittal and to assure that the information they report to the hospitals or the fiscal intermediaries complies with these instructions. Those agencies were also instructed to send this transmittal to managed care organizations with which they contract so that the managed care organizations can also take any necessary action. HCFA expects that the State Medicaid Agencies will start maintaining their systems in a way that segregates the "excluded days".

Q2. In the "Clarification for Cost Reporting Periods Beginning on or After January 1, 2000" under the heading "included days", the last sentence in the second paragraph states that " . . . you must

determine whether any of the days are dual entitlement days and, to the extent they are, subtract them from the other days included in the calculation." This seems to imply that it is the intermediaries' responsibility to determine if any patients are dual eligible (Medicaid and Medicare Part A). How are the intermediaries to make this determination?

A. HCFA will update the Hospital and Skilled Nursing Facility Audit Program to give intermediaries guidance on what procedures to use when auditing the Medicaid days used in the computation of the Medicare DSH payments.

Q3. Does a day count for the purpose of Medicare DSH payment if the patient was entitled to both Medicaid and Medicare Part B on that day?

A. Yes. Per 42 CFR 412.106(b)(4), a day does not count in the Medicare DSH payment calculation only if the patient is entitled to both Medicaid and Medicare part A on that day. The inclusion of the Medicaid days for patients entitled to Medicare Part B only in the DSH formula does not result in double counting because the Medicare Part B days are not included in the Medicare Part A/SSI portion of the formula.

Q4. Are days associated with patients in the excluded psychiatric and rehabilitation units to be excluded from the computation of the Medicare Disproportionate Share Hospital payments?

A. Yes. As mentioned in PM A-99-62 (page 3, second paragraph), the hospitals are being held harmless only for the general assistance or other

State-only health programs, charity care, Medicaid DSH, and/ or ineligible waiver or demonstration days which were included in the computation of the Medicare DSH payment and not for any other aspect of the calculation of the Medicare DSH payments. Per 42 CFR 412.106(a)(1)(ii), the number of patient days includes only those days attributable to the areas of the hospital that are subject to the prospective payment system and excludes all others. Therefore, excluded units' days have to be excluded from both the Medicaid and total inpatient days used to compute the Medicare DSH payment.

Q5. Should the intermediary treat Provider B as a new facility for FYE 12-31-98 cost report purposes and eliminate the general assistance days from the computation of the Medicare DSH payment in the following situation? Provider A sold its facility to Provider B. Provider B is now part of a chain. The rest of the facilities in the chain did not get paid for general assistance days in their settled cost reports. Provider B kept provider A's provider number and provider A's old owner included general assistance days in the computation of Medicare DSH payment in the past.

A. Since Provider B kept Provider A's provider number it should not be considered as a new provider. Therefore, if Provider A always received payment reflecting the erroneous inclusion of general assistance days in the past, the intermediary should continue to include those type of

days in the FYE 12-31-98 and 12-31-99 cost reports.

Q6. What needs to be done if in the past the FI erroneously allowed general assistance days for a number of years but upon realizing the error reopened all cost reports to exclude those days? Does it matter if the reopening happened many years back and the intermediary's policy since has been to exclude these days?

A. PM A-99-62 states in the second sentence, second paragraph on page 3 that if prior to the issuance of this PM, the intermediary reopened a settled cost report to disallow the portion of Medicare DSH payment attributable to the inclusion of these type of days, the intermediary is to reopen that cost report again and refund the amount (including interest) collected. Thus, if the cost reports which the intermediary reopened are still subject to reopening in accordance with 42 CFR 405.1885, the intermediary must reopen those cost reports.

Q7. What if we have cases where general assistance days were excluded by estimates. Are we prohibited from correcting those cost reports with accurate data? Or should we leave those cost reports for closed periods alone? How do we handle such providers' open cost reports?

A. As mentioned in the second paragraph on page 3 of PM A-99-62, the intermediary should not reopen cost reports to disallow the portion of Medicare DSH payment attributable to the erroneous inclusion of the ineligible days. Therefore, even

if the intermediary did not disallow all the ineligible days in a settled cost report because the estimates understated the number of general assistance days, that cost report should not be reopened. The intermediary also should not reopen a cost report if the estimates overstated the number of general assistance days which were disallowed unless the hospital filed a jurisdictionally proper appeal to the PRRB on this issue for that cost report before October 15, 1999.

As stated in the last sentence of the third paragraph on page 3 of PM A-99-62, the actual number of general assistance and other State-only health programs, charity care, Medicaid DSH, and/or ineligible waiver or demonstration days, as well as Medicaid Title XIX days, that the intermediary allows for open cost reports must be supported by auditable documentation provided by the hospital.

Q8. Can a hospital add general assistance and/or other ineligible days to settled cost reports for fiscal years beginning before January 1, 2000 if the intermediary did not pay for those days previously?

A. No. As stated in PM A-99-62, on or after October 15, 1999, the intermediary should not accept reopening requests on this issue.

Q9. Should an intermediary accept amended cost reports for the issue of general assistance and/or other ineligible days after October 15, 1999?

A. No. See PM A-99-62, page 3, last sentence of second paragraph and page 4, first full sentence on the page.

Q10. If prior to October 15, 1999 a hospital requested that the intermediary reopen a cost report to include general assistance days in the computation of Medicare DSH but the intermediary denied the reopening request, should the intermediary now reopen that cost report and pay the hospital?

A. Yes. The intermediary should now reopen the cost report at issue if the reopening was requested before HCFA communicated the hold harmless position (i.e., before October 15, 1999).

Q11. A provider has 180 days to file an appeal with the Provider Reimbursement Review Board (PRRB). Why must the hospital appeal before October 15, 1999 if the 180 days from the date of the Notice of Program Reimbursement for a given cost report has not expired before October 15, 1999?

A. A jurisdictionally proper appeal on the issue of general assistance or other State-only, charity care, Medicaid DSH, and/or ineligible waiver or demonstration days for a cost reporting period beginning before January 1, 2000, must have been filed before October 15, 1999 in order for the hospital to be held harmless for that specific cost report. However, if the hospital filed a jurisdictionally proper appeal on this issue before October 15, 1999 for a prior cost reporting period, the intermediary should also reopen that hospital's cost report for any cost reporting period beginning before January 1, 2000 for which an ap-

peal was filed after October 15, 1999. For example, the hospital filed a jurisdictionally proper appeal on this issue for fiscal year ended (FYE) 12-31-96 before October 15, 1999 but because the cost report for FYE 12-31-97 was settled on October 1, 1999 the hospital did not get a chance to appeal this issue for that fiscal year before October 15, 1999. In this situation, the intermediary will reopen both the FYE 12-31-96 and FYE 12-31-97 cost reports even if an appeal for the FYE 12-31-97 cost report was filed after October 15, 1999. The intermediary will not, however, reopen the FYE 12-31-97 cost report if the hospital did not appeal this issue in the FYE 12-31-96 cost report before October 15, 1999.

Q12. What is the significance of the October 15, 1999 date as it relates to appeals?

A. October 15, 1999 is the date that HCFA first communicated the hold harmless position. Therefore, in order to have an appeal resolved by the intermediary under the hold harmless rules described in PM A-99-62, a hospital must have filed an appeal on this issue for at least one of its cost reports for a cost reporting period beginning before January 1, 2000 before the October 15, 1999 date that HCFA first announced the hold harmless position.

Q13. Are we trying to prevent hospitals from filing jurisdictionally proper appeals to the PRRB on the issue of these type of ineligible days on or after October 15, 1999?

A. No. The intent of PM A-99-2 is to have the intermediaries resolve appeals which were filed before October 15, 1999 in accordance with the hold harmless provisions. The PM does not otherwise preclude the hospital from filing an appeal on this issue to the PRRB after October 15, 1999. Note also, that the PM specifics on page 4, that the intermediary will also apply the hold harmless provisions to any cost reporting period beginning before January 1, 2000 for which a jurisdictionally proper appeal was filed after October 15, 1999, if the hospital appealed before October 15, 1999, the denial of payment for these type of ineligible days in previous cost reporting periods.

Q14. Should the intermediary automatically allow the general assistance days in the final settlement of a cost report if the hospital included the general assistance days issue on the "protested amount" line, or must the hospital formally appeal this issue?

A. As specified in PM A-99-62, the hospital must have filed a jurisdictionally proper appeal on the issue of these type of ineligible days to get the benefit of the hold harmless provision. Therefore, the intermediary should not automatically include these type of days in the settlement of the cost report only because the hospital included the reimbursement effect of these type of ineligible days on the "protested amount" line.

Q15. How are the intermediaries to handle a situation where the hospital filed a jurisdictionally proper general DSH appeal without specifically addressing the ineligible days (i.e., general assistance or

other State-only health program, charity care, Medicaid DSH, and/or ineligible waiver or demonstration population days)?

A. PM A-99-62 specifies on page 3 and page 4 that the hold harmless provision applies only to jurisdictionally proper appeals on the issue of the exclusion of these types of days from the Medicare DSH formula. This reinforces the statement in the last sentence of the first paragraph on page 3 of the PM which states " . . . this decision is not intended to hold hospitals harmless for any other aspect of the calculation of Medicare DSH payments . . . ". Therefore, the intermediaries should not apply the hold harmless provisions in situations of general Medicare DSH appeals unless the hospital furnishes proof that the appeal includes the issue of these type of ineligible days. Even if the appeal is somewhat more specific and addresses Medicaid days, the intermediary should make every effort to determine whether the general assistance or other State-only health program, charity care, Medicaid DSH, and/or ineligible waiver or demonstration days are at issue. If for the Medicaid days DSH appeals it is difficult to determine whether the general assistance, etc. days are at issue, the intermediary should E-Mail or otherwise send a request for guidance to the appropriate HCFA regional office.

Q16. How are the open cost reports for fiscal years beginning prior to 1-1-00 to be handled in a situation where the intermediary disallowed the ineligible days during the audit of the latest settled

cost report (e.g., FYE 12-31-97) but allowed them in the preceding cost report(s) (e.g., FYE 12-31-96 or FYE 12-31-96 and several prior fiscal years)?

A. If before October 15, 1999 the hospital filed a jurisdictionally proper appeal on the issue of exclusion of these type of days for the FYE 12-31-97 cost report the intermediary should reopen that cost report and revise the Medicare DSH payment to reflect the inclusion of these types of days. Since the hospital established an expectation that these type of days should be included in the computation of the Medicare DSH payments, the intermediary should also continue to include these type of ineligible days in the computation of the Medicare DSH payment in the open cost reports for FYE 12-31-98 and FYE 12-31-99 as long as the hospital included these days in the "as submitted" cost reports for those years thus continuing this expectation. If the hospital abandoned its expectation of receiving payment in those open cost reports (FYE 12-31-98 and FYE 12-31-99) and did not even include this issue on the "protested amount" line, the intermediary should not continue paying the Medicare DSH adjustment reflecting the inclusion of these type of days for those years.

If the hospital did not file a jurisdictionally proper appeal before October 15, 1999 for the FYE 12-31-97 cost report on the issue of exclusion of these types of days from the Medicare DSH payment computation, its expectation is construed to have been extinguished and the intermediary should not revise the FYE 12-31-97 cost report

and should not continue to pay the Medicare DSH adjustment reflecting the inclusion of these type of days in the open cost reports (FYE 12-31-98 and 12-31-99).

Q17. If it has always been the intermediary's practice for a given hospital to exclude the ineligible days from the computation of the Medicare DSH payment but through an oversight (e.g., cost report was not audited, auditor made an error) the intermediary made payment based on the inclusion of these type of days in the Medicare DSH formula for one year, should these days, be included in the computation of the Medicare DSH payment in all the open cost reports for fiscal years beginning before January 1, 2000?

A. In accordance with PM-A-99-62, page 3, second paragraph, the intermediary should not reopen the one cost report where payment was made based on the inclusion of the ineligible days in the Medicare DSH formula. However, the erroneous payment in that one year does not establish "a practice which was followed for the hospital at issue" as intended by the phrase used in the third paragraph on page 3 of PM A-99-62. Therefore, the intermediary should not allow these type of days in the Medicare DSH calculation for open cost reports for cost reporting periods beginning before January 1, 2000, unless before October 15, 1999, the hospital filed a jurisdictionally proper appeal on the issue of these type of days for the cost reporting periods in which the intermediary denied the payment.

Q18. If appeal criteria is met, are all reopenable cost reports affected or are we just allowing the general assistance days in the years under appeal?

A. As mentioned in the first full paragraph on page 4 of PM A-99-62, the intermediary should reopen only the cost report(s) at issue in the appeal. For example, if the hospital appealed the cost report for FYE 12-31-97 but did not appeal the cost report for FYE 12-31-96, the intermediary should reopen only the cost report for FYE 12-31-97.

Q19. The hold harmless provisions described in PM A-99-62 may result in a substantial amount of money being given back to the hospitals. How is this going to be accounted for in the CASR at the end of the year? If left as is, the CASR will appear to show that the intermediaries gave money to the providers as a result of the audit effort. This will materially alter the audit effectiveness ratio. How is this going to be removed from the CASP?

A. HCFA will modify the CASR instructions through the STAR alert to accommodate this issue.

DEPARTMENT OF HEALTH
& HUMAN SERVICES
Centers for Medicare &
Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

TDL-13179, 01-18-13

MEMORANDUM

DATE: Jan. 30, 2013

FROM: Acting Director, Financial Services Group
Office of Financial Management

Director, Hospital and Ambulatory
Payment Group
Center for Medicare

Director, Medicare Contractor
Management Group
Center for Medicare

SUBJECT: Medicare Cost Report Final Settlements and Instructions Pertaining to Specific Disproportionate Share Hospitals (DSH)

TO: All Fiscal Intermediaries (FIs), and Part A and Part B Medicare Administrative Contractors (A/B MACs)

Technical Direction Letter (TDL)-13105, issued on December 17, 2012, instructed contractors to immediately stop the issuance of Notices of Program Reimbursement (NPRs) for any cost reports that utilize a Social Security Income (SSI) ratio for determining DSH hospital payments, until further notice.

Effective immediately, contractors shall resume the issuance of all NPRs, with the exception of the 29 hospitals that are plaintiffs in two recent court cases, Allina Health Services v. Sebelius and Florida Health Science Center v. Sebelius (plaintiff hospitals are listed on Attachment A). For the non-plaintiff hospitals (all hospitals except those noted on Attachment A), contractors shall issue a Notice of Intent to Reopen the cost report along with the NPR. The Notice of Intent to Reopen shall use the following reason for reopening:

> "In the event of an unfavorable final nonappealable decision in Allina Health Services v. Sebelius, the cost report will be reopened to adjust the Disproportionate Share payment calculation."

In addition to holding the NPRs for the 29 plaintiff hospitals on Attachment A, the contractors shall:

- Update the Provider Specific File in PRICER with the SSI ratios included on Attachment A within 15 business days of the issuance date of this TDL.
- Contractors shall use the SSI ratios on Attachment A when completing tentative settlements and interim rate reviews.
- For those plaintiff hospitals on Periodic Interim Payments (PIP), the contractors shall use the SSI ratios on Attachment A when completing PIP rate reviews.

The Centers for Medicare & Medicaid Services will work with the individual contractors to address any other applicable cost report holds related to DSH.

Change Request 7814 (Transmittal 1096) was issued on June 8, 2012 and included timeframes for contractors to issue NPRs based on recently released SSI ratios. Due to the delay in the issuance of NPRs due to the Allina court case, the NPR timeframes in CR 7814 will be extended by 60 days.

NOTE: MEDICARE ADMINISTRATIVE CONTRACTORS (MACs)

A/B MAC Contract Numbers

Jurisdiction F~HHSM-500-2011-M0004Z

Jurisdiction H~HHSM-500-2010-M0001Z

Jurisdiction 1~HHSM-500-2008-M0002Z

Jurisdiction 5~HHSM-500-2007-M0002Z

Jurisdiction 8~HHSM-500-2011-M0006Z

Jurisdiction 9~HHSM-500-2008-M0008Z

Jurisdiction 10~HHSM-500-2009-M0004Z

Jurisdiction 11~HHSM-500-2010-M0001Z

Jurisdiction 12~HHSM-500-2008-M0001Z

Jurisdiction 13~HHSM-500-2008-M0004Z

Jurisdiction 14~HHSM-500-2009-M0002Z

Jurisdiction 15~HHSM-500-2010-M0002Z

This Technical Direction Letter (TDL) is being issued to you as technical direction under your MAC contract and has been approved by your Contracting Officer's Representative (COR). This technical direction is not construed as a change or intent to change the scope of work under the contract and is to be acted upon only if sufficient funds are available. In this regard, your attention

is directed to the clause of the General Provisions of your contract entitled Limitation of Funds, FAR 52.232-22 or Limitation of Cost, FAR 52.232-20 (as applicable). If the Contractor considers anything contained herein to be outside of the current scope of the contract, or contrary to any of its terms or conditions, the Contractorshall immediately notify the Contracting Officer in writing as to the specific discrepancies and any proposed corrective action.

Should you require further technical clarification, you may contact your COR. Contractual questions should be directed to your CMS Contracting Officer. Please copy the COR and Contracting Officer on all electronic and/or written correspondence in relation to this technical direction letter.

If you are an FI and have any questions, please contact Dorothy Braunsar at (410) 786-4037.

/s/	/s/	/s/
Charlotte Benson	Marc Hartstein	Karen Jackson

Attachment

cc:

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Karla Thormodson, Noridian Administrative Services, LLC

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Amanda Bolger, Wisconsin Physicians Service Insurance Corporation

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Larry Leslie, Palmetto GBA, LLC

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Stacie Amburn, National Government Services, Inc.

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James Throne, CM/MCMG
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Marilyn Bryan, CM/MCMG
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Jody Kurtenbach, CM/MCMG
Larry Young, CM/MCMG
Carol Messick, CM/MCMG
Mark Korpela, OFM/FSG
Dorothy Braunsar, OFM/FSG

Attachment A				
				Revised
Provider Name	CCN	Contractor	Cont #	2010 SSI
Shands Jacksonville	100001	FCSO - J9	9001	0.21135
Mount Sinai Florida	100034	FCSO - J9	9001	0.24962
Shands UF	100113	FCSO - J9	9001	0.0969
Tampa General Hospital	100128	FCSO - J9	9001	0.12222
Henry Ford Hospital	230053	WPS - J8	8001	0.1576
Allina Cambridge	240020	Noridian - FI	320	0.02374
Allina United	240038	Noridian - FI	320	0.06178
Allina Abbott Northwestern	240057	Noridian - FI	320	0.05706
Allina Owatonna	240069	Noridian - FI	320	0.02053
Allina Unity	240132	Noridian - FI	320	0.03866
Kaleida	330005	NGS - J13	13001	0.1216
Southside Hosp.	330043	NGS - J13	13001	0.07811
NY Hosp. of Queens	330055	NGS - J13	13001	0.23337
Montefiore	330059	NGS - J13	13001	0.22562
NYPres	330101	NGS - J13	13001	0.17226
North Shore Univ.	330106	NGS - J13	13001	0.06469
Staten Island Univ.	330160	NGS - J13	13001	0.1326
Highland Hosp. of Rochester	330164	NGS - J13	13001	0.13322
Maimonides	330194	NGS - J13	13001	0.32221
Long Island Jewish	330195	NGS - J13	13001	0.13895
Kingsbrook Jewish	330201	NGS - J13	13001	0.2539
NY Methodist	330236	NGS - J13	13001	0.26723
Strong Memorial	330285	NGS - J13	13001	0.11535
Lutheran Med Ctr.	330306	NGS - J13	13001	0.24105
Forest Hills	330353	NGS - J13	13001	0.25192
Franklin Hosp.	330372	NGS - J13	13001	0.11092
North Carolina Baptist	340047	Palmetto - J11	11501	0.1138
Methodist Dallas	450051	Novitas - JH	4011	0.14836
Methodist Charlton	450723	Novitas - JH	4011	0.12596

DEPARTMENT OF HEALTH
& HUMAN SERVICES
Centers for Medicare &
Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

TDL-13056, 08/27/2013

MEMORANDUM

DATE: September 3, 2013

FROM: Director, Financial Services Group
Office of Financial Management

Director, Hospital Ambulatory
Policy Group
Center for Medicare

Director, Medicare Contractor
Management Group
Center for Medicare

SUBJECT: Instructions Pertaining to the Fiscal Year (FY) 2011 Supplemental Security Income (SSI) Ratios for the Specific Disproportionate Share Hospitals that are Plaintiffs in Two Recent Court Cases (Allina Health Services v. Sebelius and Florida Health Center v. Sebelius)

TO: See Addressees

Technical Direction Letter (TDL)-13179, issued on January 30, 2013, instructed contractors to resume the issuance of all Notices of Program Reimbursement (NPRs), with the exception of the 29 hospitals that are plaintiffs

in two recent court cases, Allina Health Services v. Sebelius and Florida Health Science Center v. Sebelius.

TDL-13179 also instructed contractors to utilize the SSI ratios included in the attachment to the TDL to update the Provider Specific File in PRICER. In addition, TDL13179 provided instructions for completing tentative settlements and interim rate reviews, including Periodic Interim Payments (PIP) rate reviews for the 29 plaintiff hospitals.

The Centers for Medicare & Medicaid Services (CMS) recently published the FY 2011 SSI ratios on its Website and issued Change Request 8406 on August 2, 2013, instructing the Medicare Administrative Contractors (MACs) to update the Provider Specific file in PRICER with these ratios. CMS is issuing this TDL to instruct MACs to continue to hold the NPRs for the 29 plaintiff hospitals listed on Attachment A. In addition, the MACs shall:

- Update the Provider Specific File in PRICER with the SSI ratios included on Attachment A within 15 business days of the issuance date of this TDL.
- MACs shall use the SSI ratios on Attachment A when completing tentative settlements and interim rate reviews.
- For those plaintiff hospitals on PIP, the MACs shall use the SSI ratios on Attachment A when completing PIP rate reviews.

Provider Education

- **No national message will be distributed .from CMS.**
- **Local contractor messaging about this TDL is prohibited.**

A/B MAC Contract Numbers

Jurisdiction 6~HHSM-500-2012-M0013Z

Jurisdiction 8~HHSM-500-2011-M0006Z

Jurisdiction 9~HHSM-500-2008-M0008Z

Jurisdiction 11~HHSM-500-2010-M0001Z

Jurisdiction H~HHSM-500-2010-M0001Z

Jurisdiction K~HHSM-500-2013-M00015Z

This Technical Direction Letter (TDL) is being issued to you as technical direction under your MAC contract and has been approved by your Contracting Officer's Representative (COR). This technical direction is not construed as a change or intent to change the scope of work under the contract and is to be acted upon only if sufficient funds are available. In this regard, your attention is directed to the clause of the General Provisions of your contract entitled Limitation of Funds, FAR 52.232-22 or Limitation of Cost, FAR 52.232-20 (as applicable). If the Contractor considers anything contained herein to be outside of the current scope of the contract, or contrary to any of its terms or conditions, the Contractor shall immediately notify the Contracting Officer in writing as to the specific discrepancies and any proposed corrective action.

Unless otherwise specified, contractors shall be in compliance with this TDL within 10 business days of its date of issuance.

Should you require further technical clarification, you may contact your COR. Contractual questions should be directed to your CMS Contracting Officer. Please copy the COR and Contracting Officer on all electronic and/or written correspondence in relation to this technical direction letter.

/s/	/s/	/s/
Charlotte Benson	Marc Hartstein	Karen Jackson

Attachment(s)

Addressees:

Todd Reiger, National Government Services, Inc.

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Stacey Greber, OAGM

Stacie Amburn, National Government Services, Inc.

Steve Stoyer, OAGM

Susan Oken, CM/MCMG

Tasha Logan, OAGM

Provider Name	CCN	Contractor	Cont #	SSI FFS Days	Total FFS Days	SSI ratio
SHANDS JACKSONVILLE MEDICAL CENTER	100001	FCSO - J9	9001	8967	41109	0.21816
MOUNT SINAI MEDICAL CENTER	100004	FCSO - J9	9001	12063	44389	0.27170
SHANDS HOSPITAL AT THE UNIVERSITY O	100113	FCSO - J9	9001	8439	73127	0.11540
TAMPA GENERAL HOSPITAL	100128	FCSO - J9	9001	8105	69732	0.11623
HENRY FORD HOSPITAL	230053	WPS - J8	6001	11014	70996	0.15806
CAMBRIDGE MEDICAL CENTER	240020	NGS - J6	6201	86	3399	0.02530
UNITED HOSPITAL	240038	NGS - J6	6201	2034	33044	0.06155
ABBOTT NORTHWESTERN HOSPITAL INC	240057	NGS - J6	6201	3283	62103	0.05286
OWATONNA HOSPITAL	240069	NGS - J6	6201	25	2296	0.01070
UNITY HOSPITAL	240132	NGS - J6	6201	435	14186	0.03073
KALEIDA HEALTH	330056	NGS - J13	13001	7946	74989	0.10599
SOUTHSIDE HOSPITAL	330043	NGS - J13	13001	2197	36377	0.06039
NEW YORK HOSPITAL MEDICAL CENTER OF	330056	NGS - J13	13001	16252	69974	0.23226
MONTEFIORE MEDICAL CENTER	330059	NGS - J13	13001	27185	120939	0.22548
NEW YORK-PRESBYTERIAN HOSPITAL	330101	NGS - J13	13001	30764	191490	0.16065
NORTH SHORE UNIVERSITY HOSPITAL	330106	NGS - J13	13001	8801	117739	0.07476
STATEN ISLAND UNIVERSITY HOSPITAL	330109	NGS - J13	13001	6986	51977	0.13446
HIGHLAND HOSPITAL	330194	NGS - J13	13001	2330	20904	0.11393
MAIMONIDES MEDICAL CENTER	330104	NGS - J13	13001	28018	76938	0.31979
LONG ISLAND JEWISH MEDICAL CENTER	330198	NGS - J13	13001	8128	58097	0.14000
KINGSBROOK JEWISH MEDICAL CENTER	330201	NGS - J13	13001	5994	22117	0.27101
NEW YORK METHODIST HOSPITAL	330236	NGS - J13	13001	16218	58892	0.27516
STRONG MEMORIAL HOSPITAL	330298	NGS - J13	13001	6021	53083	0.12652
LUTHERAN MEDICAL CENTER	330309	NGS - J13	13001	8351	38880	0.21484
FOREST HILLS HOSPITAL	330360	NGS - J13	13001	7613	31379	0.24264
FRANKLIN HOSPITAL	330972	NGS - J13	13001	2892	29880	0.10954
NORTH CAROLINA BAPTIST HOSPITAL	340047	Palmetto - J11	11501	8740	78886	0.11106
METHODIST DALLAS MEDICAL CENTER	450061	Novitas - JH	4011	5001	31366	0.15947
METHODIST CHARLTON MEDICAL CENTER	450723	Novitas - JH	4011	3652	27907	0.13088

No. 17-1484

In the Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE PETITIONER

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QUESTION PRESENTED

The Department of Health and Human Services (HHS) must use notice-and-comment rulemaking to promulgate any rule, requirement, or statement of policy that "establishes or changes a substantive legal standard" governing payment for services under the Medicare Act. 42 U.S.C. 1395hh(a)(2). And if a "final regulation" is not a "logical outgrowth" of the notice of proposed rulemaking, it "shall not take effect" without a further notice-and-comment opportunity. 42 U.S.C. 1395hh(a)(4).

The Centers for Medicare & Medicaid Services (CMS) within HHS instructs private contractors how to determine Medicare payments owed to participating hospitals, including by making available certain intermediate calculations that might affect a hospital's ultimate reimbursement. A hospital dissatisfied with the contractor's payment determination generally can seek both administrative and judicial review, and neither the payment determination nor CMS's intermediate calculation is binding on HHS or the courts. Respondents are hospitals who have challenged CMS's intermediate calculations that it furnished to its contractors to determine respondents' payments for fiscal year 2012. The question presented is:

Whether 42 U.S.C. 1395hh(a)(2) or 1395hh(a)(4) required the Department of Health and Human Services to conduct notice-and-comment rulemaking before providing the challenged instructions to a Medicare Administrator Contractor making initial determinations of payments due under Medicare.

PARTIES TO THE PROCEEDING

Petitioner is Alex M. Azar II, in his official capacity of Secretary of Health and Human Services.

Respondents are Allina Health Services, doing business as United Hospital, Unity Hospital, and Abbott Northwestern Hospital; Florida Health Sciences Center, Inc., doing business as Tampa General Hospital; Montefiore Medical Center; Mount Sinai Medical Center of Florida, Inc., doing business as Mount Sinai Medical Center; New York Hospital Medical Center of Queens; New York Methodist Hospital; and New York and Presbyterian Hospital, doing business as New York Presbyterian Hospital Weill Cornell Medical Center.

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In the Supreme Court of the United States

No. 17-1484

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-18a) is reported at 863 F.3d 937. The opinion of the district court (Pet. App. 19a-44a) is reported at 201 F. Supp. 3d 94. The decisions of the Provider Reimbursement Review Board (Pet. App. 47a-61a, 62a-76a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on July 25, 2017. A petition for rehearing was denied on November 29, 2017 (Pet. App. 77a-80a). On February 21, 2018, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including March 29, 2018. On March 22, 2018, the Chief Justice further extended the time to and including April 27, 2018, and the petition was filed on that date. The petition for a writ of certiorari was granted on September 27, 2018. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant statutory and regulatory provisions are reproduced in the appendix to this brief. App., *infra*, 1a-27a.

STATEMENT

This case concerns the scope of the notice-and-comment rulemaking requirements that the Department of Health and Human Services (HHS) must follow in administering the Medicare Act, *i.e.*, Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.* "Under the Medicare program, certain qualified providers of health care services are reimbursed" by HHS for "providing covered services to Medicare beneficiaries." *Bethesda Hosp. Ass'n* v. *Bowen*, 485 U.S. 399, 400 (1988) (citation omitted). HHS hires private contractors to make an initial determination of the reimbursement amount to be paid to each provider, which the provider then can generally challenge in an administrative appeal and ultimately on judicial review. *Id.* at 400-401. The issue in this case is whether, under a special rulemaking provision of the Medicare Act, 42 U.S.C. 1395hh, HHS's instructions to its own contractors regarding the calculation of reimbursements, which are not legally binding on either the agency or the courts on subsequent review, must be issued as published regulations after notice-and-comment rulemaking.

1. a. Medicare Part A "covers institutional health costs such as hospital expenses" for certain disabled and 65-and-over persons. *United States* v. *Erika, Inc.*, 456 U.S. 201, 202 (1982); see 42 U.S.C. 1395c *et seq.*[1]

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[1] Medicare Part B, 42 U.S.C. 1395j *et seq.*, not at issue here, "supplements Part A's coverage by insuring against a portion of some

Qualifying hospitals are generally "reimbursed a fixed amount" for covered services they provide to Medicare beneficiaries, "regardless of actual cost." *Good Samaritan Hosp.* v. *Shalala*, 508 U.S. 402, 406 n.3 (1993); see 42 U.S.C. 1395ww(d); 42 C.F.R. 412.1(a)(1). In addition to the fixed amount, hospitals may receive an "additional payment" each year if they "serve[] a significantly disproportionate number of low-income patients." 42 U.S.C. 1395ww(d)(5)(F)(i)(I).

A hospital's eligibility for (and the amount of) the additional payment in a given year is determined in part by a statutorily defined fraction meant to roughly approximate the proportion of Medicare patients the hospital served during that year who are low-income. 42 U.S.C. 1395ww(d)(5)(F)(v) and (vi). The fraction uses a proxy for low-income patients: those entitled to supplemental security income (SSI) benefits under Title XVI of the Social Security Act, 42 U.S.C. 1381 *et seq.*, which are available "to financially needy individuals who are aged, blind, or disabled." *Bowen* v. *Galbreath*, 485 U.S. 74, 75 (1988). The numerator of the fraction is therefore the number of patient days of patients who were *both* "entitled to benefits under part A" *and* "entitled to [SSI] benefits" during the relevant time period. 42 U.S.C. 1395ww(d)(5)(F)(vi)(I). The denominator is the number of patient days of all patients who were "entitled to benefits under part A," whether or not they were entitled to SSI benefits. *Ibid.* This is called the "SSI fraction" or the "Medicare fraction," the term used in this brief.[2]

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medical expenses, such as certain physician services and X-rays, that are excluded from the Part A program." *Erika, Inc.*, 456 U.S. at 202.

[2] A related formula, the "Medicaid fraction," also helps determine a hospital's "additional payment" for serving low-income patients.

In 1997, Congress amended the Medicare Act to add Medicare Part C, 42 U.S.C. 1395w-21 *et seq.*, "which gives Medicare beneficiaries an alternative to the traditional Part A fee-for-service system." *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Under Part C, an individual enrolls in a private healthcare plan, and HHS generally makes payments to that plan instead of directly paying the healthcare provider (as it does under Part A). *Id.* at 2-3. But payments for covered inpatient hospital services under Part C are still paid from the Part A Trust Fund. 42 U.S.C. 1395w-23(f). And to be eligible to have healthcare benefits administered under Part C, an individual must be "entitled to benefits under part A." 42 U.S.C. 1395w-21(a)(3)(A) (2012).

The underlying interpretive issue in this case is whether a Part C patient, who as just noted must be "entitled to benefits under part A," 42 U.S.C. 1395w-21(a)(3)(A) (2012), is properly regarded as "entitled to benefits under part A" for purposes of calculating the Medicare fraction, 42 U.S.C. 1395ww(d)(5)(F)(vi)(I). If, as the court of appeals assumed, "Part C enrollees [are] wealthier than Part A enrollees," Pet. App. 4a, the inclusion of Part C patients in the Medicare fraction would—if the assumption is true—tend to reduce the value of the fraction (and thus possibly reduce the amount of respondents' "additional payment," 42 U.S.C. 1395ww(d)(5)(F)(i)). But see 78 Fed. Reg. 50,496, 50,615 (Aug. 19, 2013) (noting that recent "research * * * has shown that Part C enrollees tend to

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42 U.S.C. 1395ww(d)(5)(F)(i) and (vi)(II). The numerator of the Medicaid fraction is the number of patient days of patients who are eligible for Medicaid but who are "*not* entitled to benefits under part A." 42 U.S.C. 1395ww(d)(5)(F)(vi)(II) (emphasis added). The denominator is the hospital's total number of patient days for all patients. *Ibid.*

have lower incomes at similar rates as Medicare beneficiaries who are not enrolled in Part C").

b. HHS administers the Medicare program through the Centers for Medicare & Medicaid Services (CMS). CMS, in turn, contracts with private contractors—formerly called "fiscal intermediaries"—that "act on behalf of CMS in carrying out certain administrative responsibilities." 42 C.F.R. 421.5(b); see 42 U.S.C. 1395kk-1(a)(1). Such contractors, like CMS's own personnel, are "required to follow Federal laws, regulations and [CMS] manual instructions" when performing such functions on behalf of CMS. 74 Fed. Reg. 65,296, 65,312 (Dec. 9, 2009). CMS has dozens of manuals, including most notably the Provider Reimbursement Manual, which "provides guidelines and policies to implement Medicare regulations." CMS, Provider Reimbursement Manual—Part 1, Doc. 15-1, at I (Foreword); see *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995).[3] As relevant here, the private contractors determine in the first instance "the amount of the payments required pursuant to [the Medicare Act] to be made to providers of services." 42 U.S.C. 1395kk-1(a)(4)(A).

i. To receive payment for providing inpatient hospital services to Medicare beneficiaries, a hospital must submit an annual cost report to the appropriate contractor. *Bethesda Hosp. Ass'n*, 485 U.S. at 400-401; see 42 C.F.R. 405.1801(b)(1). The contractor reviews the cost report and issues a written notice to the hospital specifying the hospital's reimbursement for the year. 42 C.F.R. 405.1803(a) and (2).

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[3] The Medicare Provider Reimbursement Manual is available at www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals.html.

The contractor, however, lacks the information necessary to determine a hospital's Medicare fraction, which requires data from the "SSI file" maintained by the Social Security Administration. 51 Fed. Reg. 16,772, 16,777 (May 6, 1986); see Pet. App. 105a ¶ 7. CMS therefore itself obtains the SSI information from that file and calculates the Medicare fraction for each hospital. 42 C.F.R. 412.106(b)(2); 42 C.F.R. 412.106(b)(2) (2003). CMS then makes those fractions available to the contractor. A contractor in turn uses a given healthcare provider's Medicare fraction as one of several inputs to a series of further calculations to determine that provider's overall Medicare reimbursement for the cost year. See 42 C.F.R. 412.106(b)(4)-(5), (c), and (d); 42 C.F.R. 412.106(b)(4)-(5), (c), and (d) (2003).

ii. Subject to an amount-in-controversy threshold, a provider dissatisfied with a contractor's determination of the total amount of its reimbursement for the year may appeal to the Provider Reimbursement Review Board. 42 U.S.C. 1395*oo*(a) and (d); 42 C.F.R. 405.1835(c). In rendering a decision, the Board must apply the provisions of the Medicare Act, agency regulations, and formal CMS Rulings issued by the CMS Administrator. 42 C.F.R. 405.1867. But interpretive rules and provisions in CMS manuals do not bind the Board, although they receive great weight. *Ibid.*

If the Board determines on appeal that it lacks "authority to decide" a relevant "question of law or regulations" (or if it fails to issue a decision within 30 days of a provider's request for such a determination), the provider may seek immediate judicial review of the "action of [the contractor]" that implicates that question. 42 U.S.C. 1395*oo*(f)(1); see 42 C.F.R. 405.1842(a) and (h), 405.1875(a)(2)(iii). Otherwise, the Board issues its

final decision on the merits. The Secretary (acting through the CMS Administrator) may, within 60 days, reverse, affirm, or modify the Board's decision. 42 U.S.C. 1395*oo*(f)(1); see 42 C.F.R. 405.1875.

iii. The final agency decision is then subject to review in district court under the standards for review in the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.* See 42 U.S.C. 1395*oo*(f)(1).

c. Before Part C was enacted in 1997, CMS or its predecessor entity within HHS calculated the Medicare fraction simply "by matching data from the Medicare Part A * * * file with the Social Security Administration's * * * SSI file" to match "individuals who are SSI recipients" with "the Medicare Part A beneficiaries who received inpatient hospital services." 51 Fed. Reg. at 16,777 (1986 interim final rule). "Thus, if a Medicare beneficiary [wa]s eligible for SSI benefits * * * during a month in which the beneficiary [wa]s a patient in the hospital, the covered Medicare Part A inpatient days of hospitalization in that month [were] counted" in the Medicare fraction. *Ibid.*

In 1990, in response to comments, the agency clarified in issuing a final rule that certain Medicare patients "who receive care at a qualified HMO" (health maintenance organization) under 42 U.S.C. 1395mm, a precursor to Part C, were "'entitled to benefits under Part A'" for purposes of the Medicare fraction. 55 Fed. Reg. 35,990, 35,994 (Sept. 4, 1990) (citation omitted) (final rule). That is because, as would later be the case under Part C, individuals could choose this HMO option only if they were "entitled to benefits under part A." 42 U.S.C. 1395mm(d). In promulgating the 1990 regulation, the agency made clear that (once it had resolved some database problems) it "ha[d] been including HMO days in

[the] SSI/Medicare" fraction. 55 Fed. Reg. at 35,994. The agency's decision was based on its interpretation of the Medicare Act: "Based on the language of [42 U.S.C. 1395ww(d)(5)(F)(vi)], which states that that the [Medicare fraction] should include 'patients who were entitled to benefits under Part A', we believe it is appropriate to include the days associated with Medicare patients who receive care at a qualified HMO" under Section 1395mm in the Medicare fraction. 55 Fed. Reg. at 35,994.

When Part C was enacted in 1997, the agency did not immediately address whether to include Part C patient days in the Medicare fraction, as it had done for HMO patient days in 1990. See *Northeast Hosp.*, 657 F.3d at 14-15. Nor did it take any steps to ensure that Part C claims were included in the Medicare databases; as a result, Part C patient days were not included in the Medicare fractions CMS computed. *Id.* at 15. In 2003, however, after "receiv[ing] questions whether patients enrolled in [Part C] should be counted in the Medicare fraction," CMS chose to address that question through the notice-and-comment process, proposing a rule that would have *excluded* Part C patient days from the fraction. 68 Fed. Reg. 27,154, 27,208 (May 19, 2003).

In 2004, after considering public comments—several of which disagreed with its earlier proposal—CMS concluded that Part C patients are "entitled to benefits under part A" within the meaning of the statutory Medicare-fraction provision, 42 U.S.C. 1395ww(d)(5)(F)(vi). See 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004). CMS therefore announced that, consistent with its 1990 final rule regarding HMO patient days, it would count Part C patient days in the Medicare fraction. *Ibid.*; see 42 C.F.R. 412.106(b)(2)(i)(B) and (iii)(B).

In 2012, a district court (in a separate case) vacated that 2004 final rule based on its determination that it was not a "logical outgrowth" of CMS's 2003 proposal, and it ordered CMS to "recalculate the [plaintiff] hospitals' reimbursements using the alternate methodology," *i.e.*, to exclude Part C patient days from the Medicare fraction. See *Allina Health Servs.* v. *Sebelius*, 746 F.3d 1102, 1105, 1111 (D.C. Cir. 2014) (describing decision). The D.C. Circuit affirmed the district court's holding that the 2004 final rule was not a "logical outgrowth" of the 2003 proposal. *Id.* at 1107-1109. But the court of appeals vacated the district court's directive that CMS exclude Part C days from the Medicare fraction, explaining that "the Secretary might achieve the same result [he originally reached] through adjudication" of the fiscal-year 2007 cost reports at issue in that case. *Id.* at 1111. On remand, the CMS Administrator, acting for the Secretary, did just that: interpreting the Medicare-fraction statute in the course of the agency's adjudication of the plaintiff hospitals' FY2007 cost reports, the CMS Administrator concluded that Part C patient days *are* properly included in the Medicare fraction. *Allina Health Servs.* v. *Burwell*, No. 2010-D38-R, at 24-46 (CMS Adm'r 2015), judicial review pending, No. 16-cv-150 (D.D.C. filed Jan. 29, 2016).[4]

Meanwhile, despite HHS's disagreement with the view that the 2004 final rule was not a logical outgrowth of its proposed rule, cf. *Long Island Care at Home, Ltd.*

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[4] The Administrator's decision is available at www.cms.gov/Regulations-and-Guidance/Review-Boards/OfficeAttorneyAdvisor/OAA-Decisions-Items/2010-D38-R.html. The district court proceedings are stayed pending the disposition of this case. See 10/4/18 Minute Order, *Allina Health Servs.* v. *Burwell*, No. 16-cv-150 (D.D.C.).

v. *Coke*, 551 U.S. 158, 174-175 (2007), the agency instituted new notice-and-comment rulemaking "in an abundance of caution." 78 Fed. Reg. at 50,614-50,615. In 2013, HHS promulgated a final rule in which the agency again concluded that Part C patients "are 'entitled to benefits under Part A'" within the meaning of the Medicare-fraction provision. *Id.* at 50,614-50,615, 50,620. The 2013 final rule applies prospectively "for FY 2014 and subsequent years." *Id.* at 50,619. Hospitals have challenged the 2013 final rule in a separate civil action that remains pending. See Second Am. Compl. ¶¶ 5, 58-62, *Florida Health Sciences Ctr., Inc.* v. *Azar*, No. 17-cv-1751 (D.D.C. Mar. 13, 2018).

2. a. In the interim, as a result of the vacatur of CMS's 2004 final rule, there was once again no binding CMS regulation governing whether Part C patient days were to be included in the Medicare fraction for fiscal years from 2004 to 2013. Yet CMS remained obligated to calculate annual Medicare fractions to enable the private contractors to make the initial determination of each hospital's appropriate Medicare reimbursement. See Pet. App. 105a ¶ 6.

That was the state of affairs in June 2014, when CMS calculated the FY2012 Medicare fractions for hospitals nationwide (including hospitals operated by respondents) and published those fractions in a spreadsheet posted on its website. Pet. App. 5a-6a, 24a. The agency did not calculate the FY2012 Medicare fractions by relying on the vacated 2004 rule. *Id.* at 105a ¶ 7; see *id.* at 30a-31a. Rather, the spreadsheet included a note explaining that the "[c]alculations * * * includ[ed] [Part C] Claims Submissions." CMS, *DSH Adjustment and 2011-2012 File*, www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html. That

notation reflected CMS's "decision * * * to include Part C days" in calculating the FY2012 Medicare fractions based on the agency's independent "'interpretation of the statute'" requiring the inclusion of "'Part C days * * * in the Medicare fraction.'" Pet. App. 33a (citation omitted); see *id.* at 5a-6a.

b. Respondents challenged CMS's calculation of their FY2012 Medicare fractions by seeking administrative review by the Provider Reimbursement Review Board. See Pet. App. 47a-48a, 62a-63a. The Board concluded that it lacked authority to decide that legal challenge and granted respondents' request for expedited judicial review under 42 U.S.C. 1395*oo*(f)(1). Pet. App. 57a-58a, 72a-73a.

3. a. Respondents accordingly filed this action for judicial review in district court. See Pet. App. 25a-26a. Among other things, respondents argued that the Medicare Act's rulemaking provision in 42 U.S.C. 1395hh required that the agency engage in notice-and-comment rulemaking before it could base its calculations of respondents' FY2012 Medicare fractions on its interpretation of the Act. See Pet. App. 35a-36a.

Section 1395hh governs rulemaking procedures under the Medicare Act. 42 U.S.C. 1395hh. Subsection (a)(1) grants the Secretary authority to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [the Medicare Act]." 42 U.S.C. 1395hh(a)(1). Subsection (b) describes the procedures such "regulations" must follow, requiring the Secretary to publish "notice of the proposed regulation in the Federal Register" and provide a public comment period of "not less than 60 days" "before issuing in final form any regulation under subsection (a)." 42 U.S.C. 1395hh(b)(1). This notice-and-comment

requirement is subject to certain exceptions, 42 U.S.C. 1395hh(b)(2), including one for circumstances in which the APA's good-cause exception, 5 U.S.C. 553(b)(B), would not require notice-and-comment rulemaking under the APA. 42 U.S.C. 1395hh(b)(2)(C). And subsection (a)(4) provides that if a provision in a "final regulation" "is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule," the provision "shall not take effect until there is the further opportunity for public comment." 42 U.S.C. 1395hh(a)(4).

But not every Medicare rule or guidance document need be promulgated as a "regulation" under these procedures. Subsection (a)(2) specifies the ones that do:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that *establishes or changes a substantive legal standard* governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [the Medicare Act] shall take effect unless it is promulgated by the Secretary by regulation under [Section 1395hh(a)(1)].

42 U.S.C. 1395hh(a)(2) (emphasis added). The italicized text is at issue in this case.

b. The district court granted summary judgment to the Secretary. Pet. App. 19a-44a. The court held that CMS's calculation of the FY2012 Medicare fractions by "includ[ing] Part C days," *id.* at 33a, did not require notice-and-comment rulemaking. *Id.* at 34a-36a. The court concluded that Section 1395hh does not apply to "'interpretive rules'" and that CMS's "interpretation of the [Medicare] statute" in the course of calculating the

Medicare fractions that it furnished to the private contractors "is not a 'rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard'" within the meaning of Section 1395hh(a)(2). *Id.* at 35a-36a (citations omitted).

The district court rejected respondents' substantive challenge to the agency's interpretation of the Medicare-fraction statute, Pet. App. 39a-44a, holding that the agency had permissibly concluded that "patients enrolled in Part C continue to be 'eligible' for Part A" within the meaning of that provision, *id.* at 44a.

4. The court of appeals reversed and remanded. Pet. App. 1a-18a. As relevant here, the court held that Section 1395hh required HHS to conduct notice-and-comment rulemaking before providing the contractors with CMS's calculation of each respondent's FY2012 Medicare fraction based on the agency's interpretation of the statute. *Id.* at 11a-18a.

a. The court of appeals determined that CMS had "establishe[d]" or "change[d]" a "'substantive legal standard'" within the meaning of Section 1395hh(a)(2) by including "Part C days in the fiscal year 2012 Medicare fractions" it furnished to its contractors. Pet. App. 13a-14a. The court rested that holding on a dictionary definition of "substantive law," which, according to *Black's Law Dictionary* 1658 (10th ed. 2014), is a "law that 'creates, defines, and regulates the rights, duties, and powers of parties.'" Pet. App. 13a-14a. Applying that definition, the court concluded that the agency's "2012 Medicare fractions" qualified as a "'substantive legal standard'" because, in the court's view, they "define the scope of hospitals' legal rights to payment for treating low-income patients." *Id.* at 14a.

The court of appeals rejected the government's contention that Section 1395hh's notice-and-comment requirement for regulations establishing or changing a "substantive legal standard," 42 U.S.C. 1395hh(a)(2), does not apply to "interpretive rules." Pet. App. 15a-17a. The court reasoned that Section 1395hh uses "different language" than the APA's rulemaking provision and, unlike the APA's rulemaking provision, does not expressly "include an exception for interpretive rules." *Id.* at 15a-16a. The court also noted that Section 1395hh(b)(2) "incorporates the APA's 'good cause' exception" in 5 U.S.C. 553(b)(B), which in the court's view showed that "Congress knew how to incorporate the APA's notice-and-comment exceptions * * * when it wanted to." Pet. App. 16a. In light of its holding that Section 1395hh requires notice-and-comment rulemaking even for interpretive rules, the court stated that it "need not decide" if HHS's inclusion of Part C days in the FY2012 Medicare fractions it furnished to its contractors was an "interpretive rule." *Id.* at 15a.

b. The court of appeals further held that "even if HHS were correct" that Section 1395hh(a)(2) does not apply to "interpretive rules," Section 1395hh(a)(4) would separately require notice-and-comment rulemaking. Pet. App. 17a-18a. Because the court in an earlier case had vacated HHS's 2004 rule announcing its interpretation of the Medicare fraction on the ground that the final rule was "not a logical outgrowth of the proposed rule," *id.* at 18a (citation omitted); see pp. 8-9, *supra*, the court concluded that Section 1395hh(a)(4) "applies with full force" and requires a "'further opportunity for public comment and a publication of the provision again as a final regulation' before HHS could re-impose the rule," Pet. App. 18a (citation omitted). CMS, the court added,

"could not circumvent this requirement by claiming that it was acting by way of adjudication rather than rulemaking," because Section 1395hh(a)(4) "says that the vacated rule may not 'take effect' at all until there has been notice and comment." *Ibid.*

SUMMARY OF ARGUMENT

CMS provides calculations of Medicare fractions for its contractors to use in making one aspect of their initial determinations of payments to be made to providers of Medicare Part A services, subject to further administrative and judicial review. Neither subsection (a)(2) nor subsection (a)(4) of 42 U.S.C. 1395hh required HHS to use notice-and-comment rulemaking procedures in adopting the interpretation of the statute reflected in those payment calculations.

1. Subsection (a)(2) did not require notice-and-comment rulemaking here because the nonbinding interpretation of the Medicare Act reflected in the calculations CMS furnished to its own contractors did not establish or change a substantive legal standard.

a. i. The phrase "establishes or changes a substantive legal standard" in subsection (a)(2) excludes nonbinding interpretations of the Medicare Act. 42 U.S.C. 1395hh(a)(2). Congress enacted subsection (a)(2) against the backdrop of 40 years of administrative law under the APA. A "central distinction" in the APA is between "'substantive rules'" and "'interpretive rules.'" *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 301 (1979) (citation omitted). Substantive rules (sometimes called "legislative rules") are binding and have the force and effect of law. *Id.* at 302-303. Interpretive rules, by contrast, merely reflect "the agency's construction of the statutes and rules which it administers." *Perez* v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1204 & n.1 (2015) (citation omitted). They do not

have the force and effect of law. *Id.* at 1208. It follows that an interpretive rule is, by definition, incapable of "establish[ing] or chang[ing] a substantive legal standard." 42 U.S.C. 1395hh(a)(2). Only a substantive rule can do that. Interpretive rules are therefore outside the scope of subsection (a)(2) and so need not be promulgated through notice-and-comment rulemaking.

It is of no moment that subsection (b)(2) incorporates the APA's exception to the notice-and-comment requirement for "good cause," but not the APA's exception for interpretive rules. Section 1395hh's notice-and-comment provision applies only to "rule[s] * * * that establish[] or change[] a substantive legal standard," which already excludes interpretive rules. 42 U.S.C. 1395hh(a)(2). An additional express exception for interpretive rules would be redundant.

ii. The drafting history of Section 1395hh(a)(2) confirms that it does not apply to interpretive rules. Subsection (a)(2) was enacted in response to a 1982 HHS proposal to do away with a self-imposed undertaking to follow APA notice-and-comment rulemaking for Medicare regulations whenever the costs "outweigh[ed]" the benefits. 47 Fed. Reg. 26,860, 26,860 (June 22, 1982). In enacting subsection (a)(2), there is no indication that Congress intended to import anything other than the established APA rulemaking requirements into the Medicare Act. Indeed, Congress rejected broad language that would have subjected any rule that "may have" a "significant effect" on Medicare payments to notice-and-comment rulemaking, instead choosing to limit the requirement for such rulemaking to rules that "establish[] or change[] a substantive legal standard governing" Medicare payments. 42 U.S.C. 1395hh(a)(2). Congress also drafted the language in subsection (a)(2) to

"reflect[] recent court rulings." H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. 566 (1987). Those rulings, including a significant opinion from the D.C. Circuit, uniformly applied well-settled law under the APA to hold that "substantive rule[s]" that have "the force of law" and "establish[] a standard of conduct" must go through notice and comment, while interpretive rules need not. *American Hosp. Ass'n* v. *Bowen*, 834 F.2d 1037, 1045-1046 (D.C. Cir. 1987) (citation omitted).

b. Section 1395hh(a)(2) did not require notice-and-comment rulemaking here. The challenged agency action here is, at most, an interpretive rule. It merely reflects "'the agency's construction of the'" Medicare Act and directly "implements the statutory" command to count patient days for patients entitled to benefits under part A in the Medicare fraction. *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 98-99 (1995). And it does not have the force and effect of law because neither the calculated Medicare fractions nor the contractors' ultimate reimbursement determinations are binding on the agency or on the courts in subsequent review. In fact, the challenged action here is not a "rule, requirement, or other statement of policy" to which Section 1395hh(a)(2) applies in the first place. 42 U.S.C. 1395hh(a)(2). The court of appeals' conclusion that it was a "requirement" because the calculated FY2012 Medicare fractions were binding on the *contractors* is erroneous; in context, "requirement" must mean a requirement imposed on *providers*, not the agency's own contractors. That is the only reading that can be reconciled with Congress's express authorization of the use of private contractors, see 42 U.S.C. 1395kk-1, which therefore act on behalf of the agency itself.

c. The court of appeals' contrary conclusion suffers from additional defects that would substantially undermine the agency's ability to administer the Medicare program. Its holding that the agency can issue instructions to its own contractors only through notice-and-comment rulemaking would, if taken to its logical conclusion, require CMS to promulgate all of its manuals and instructions, including the Provider Reimbursement Manual, through notice and comment. Not only is that at odds with this Court's decision in *Guernsey Memorial Hospital*; it would cripple effective administration of the Medicare program. Also, under the court of appeals' logic, if the agency's calculation of Medicare fractions *including* Part C patients "change[d]" a "substantive legal standard," then the agency's pre-2004 practice of *excluding* Part C patients from the fraction must have "establish[ed]" a "substantive legal standard." But the agency never promulgated its pre-2004 practice through notice-and-comment rulemaking either. This anomaly would mean that the agency was legally prohibited from determining a hospital's additional payment for serving a disproportionate share of low-income patients without notice-and-comment rulemaking—a result that would be entirely at odds with the Medicare Act's directive that "the Secretary *shall* provide * * * for an additional payment" to hospitals using the statutorily defined Medicare fraction, 42 U.S.C. 1395ww(d)(5)(F)(i) (emphasis added).

2. Section 1395hh(a)(4) did not require notice-and-comment rulemaking here either.

a. Subsection (a)(4) did not provide an independent basis for requiring notice-and-comment rulemaking. By its terms, it applies only "[i]f the Secretary publishes

a final regulation." 42 U.S.C. 1395hh(a)(4). But the Secretary did not publish CMS's calculation of respondents' FY2012 Medicare fractions—or the nonbinding statutory interpretation underlying that calculation—as a final regulation. Subsection (a)(4) thus did not apply. And, as the district court determined, the FY2012 calculations were not based on the vacated 2004 rule, and so did not give "effect" to that rule.

b. Even if subsection (a)(4) had independent force, it would not have applied here because the agency chose to proceed by adjudication rather than by rulemaking. Agencies are generally free to choose between rulemaking and adjudication. *SEC* v. *Chenery Corp.*, 332 U.S. 194 (1947). That remains true even if rulemaking would be more efficient, and even if the agency previously had acted (or attempted to act) through rulemaking. *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 292 (1974). Nor did the agency's adjudication of the FY2012 Medicare fractions at issue in this case "circumvent" the vacatur of the 2004 rule, as the court of appeals thought. To the contrary, once the 2004 rule had been vacated, the agency had no choice but to act through adjudication because the Medicare Act imposes a *duty* on the Secretary to compute providers' "additional payment[s]" for serving a disproportionate number of low-income patients. 42 U.S.C. 1395ww(d)(5)(F)(i). And indeed the agency's adjudication of respondents' FY2012 Medicare fractions is consistent with a 1990 final rule that included in the Medicare fraction patient days for analogous patients enrolled in HMOs.

ARGUMENT

I. SECTION 1395hh(a)(2) DID NOT REQUIRE NOTICE-AND-COMMENT RULEMAKING FOR CMS TO FURNISH THE CHALLENGED INSTRUCTIONS TO ITS CONTRACTORS

Section 1395hh(a)(2) requires notice-and-comment rulemaking only for a "rule, requirement, or other statement of policy" that "establishes or changes" certain "substantive legal standard[s]" under the Medicare Act. 42 U.S.C. 1395hh(a)(2). By definition, however, an agency's nonbinding interpretation of a statute cannot "establish[] or change[]" a "substantive legal standard." So it is with the agency action at issue here. CMS's calculation of Medicare fractions for each hospital, based on the agency's interpretation of the Medicare Act (and furnished to the contractor that makes the initial determinations of the reimbursement amounts to be paid to the hospital) does not establish or change any substantive legal standard. The *statute* establishes the governing standard. CMS's calculation of the Medicare fraction is simply one aspect of the contractor's initial determination of the hospital's total reimbursement for the year. And both CMS's calculation and CMS's statutory interpretation on which the calculation is based are subject to administrative review by the Provider Reimbursement Review Board and to judicial review in district court—and both the calculation and the interpretation can be revised at either stage of review. That makes it all the more clear that the calculation does not—indeed cannot—establish or change a substantive legal standard.

To be sure, CMS's calculation of the Medicare fractions is binding on the contractors—both because the contractors do not have access to the necessary data

and to promote uniformity in the contractors' initial determinations of the reimbursement amounts. But the court of appeals' reasoning that CMS was therefore required to conduct notice-and-comment rulemaking before it could furnish that information to its own contractors would, if taken to its logical conclusion, subject the entire panoply of Medicare contractor guidelines and manuals, including the Provider Reimbursement Manual, to Section 1395hh's notice-and-comment requirements. Indeed, in this case, the court of appeals' reasoning would mean that CMS could not instruct its contractors to follow the interpretation of the statute that *respondents* urge without going through notice-and-comment rulemaking. Such a reading of Section 1395hh would cripple effective administration of the vast and complex Medicare program and cannot be what the statutory text effects.

A. The Notice-And-Comment Procedures In Section 1395hh Do Not Apply To Nonbinding Interpretations of the Medicare Act

Section 1395hh requires notice-and-comment rulemaking for "rule[s], requirement[s], or other statement[s] of policy" that "establish[] or change[]" certain "substantive legal standard[s]" under the Medicare Act. 42 U.S.C. 1395hh(a)(2). Congress enacted that provision in 1987 against an established body of administrative law under the APA, and adopted statutory text reflecting APA jurisprudence at that time. Section 1395hh's text, surrounding legal context, and drafting history all demonstrate that the agency's nonbinding interpretation of a statute—which by definition lacks the force and effect of law—does not establish or change a "substantive legal standard" under Section 1395hh(a)(2).

1. The statutory phrase "establishes or changes a substantive legal standard" excludes nonbinding interpretations of the Medicare Act

a. When Congress required rules that "establish[] or change[]" certain "substantive legal standard[s]" to be promulgated through notice-and-comment rulemaking, 42 U.S.C. 1395hh(a)(2), it necessarily excluded the agency's nonbinding interpretations of the Medicare statute. That is because, by definition, an interpretation of a statute cannot establish or change a substantive legal standard. Rather, *the statute* supplies the substantive legal standard. The interpretation simply reflects the understanding on which the agency will base its "implement[ation]" of that standard. *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 98 (1995). It does not establish or change that standard.[5]

Here, after all, CMS must rely on *some* interpretation of the Medicare Act in instructing the contractors in making their initial determinations. But such an interpretation—whether reflected in the calculation of Medicare fractions as in this case, or contained in the Provider Reimbursement Manual as in other cases—is not binding in final agency review, or in court, or on the hospital or other healthcare provider. A *nonbinding* interpretation by definition "do[es] not have the force and effect of law" and so cannot establish or change any kind of legal standard. *Perez* v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (citation omitted).

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[5] This case involves action by CMS that rests on an interpretation of the Medicare Act itself, and this brief accordingly discusses the application of Section 1395hh to interpretations of the Act. The same analysis would apply, however, to action by CMS interpreting a regulation that was promulgated to implement the Act.

The fundamental distinction between establishing or changing a substantive legal standard, on the one hand, and nonbinding statutory interpretation, on the other, tracks the "central distinction" in the APA between "'substantive'" and "'interpretive'" rules. *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 301 (1979) (citation omitted); see U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 30 & n.3 (1947) (1947 APA Manual).[6] Section 1395hh's notice-and-comment provisions were enacted against the backdrop of decades of APA jurisprudence, and so must be interpreted in that light.

Under the APA, only substantive rules must go through notice-and-comment rulemaking. *Chrysler Corp.*, 441 U.S. at 313, 315. Substantive rules are ones that "have the 'force and effect of law.'" *Id.* at 295. A "substantive rule—or a 'legislative-type rule'"—has binding legal force because it has been promulgated pursuant to a congressional grant of "quasi-legislative authority" and "conform[s] with [the] procedural requirements" that Congress has provided for its promulgation, which normally include the APA's notice-and-comment requirements. *Id.* at 302-303 (citation omitted); see *id.* at 313.

Interpretive rules, by contrast, generally need not go through notice-and-comment rulemaking under the APA. 5 U.S.C. 553(b)(A). "[I]nterpretive rules" reflect "'the agency's construction of the statutes and rules which it administers.'" *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204 (quoting *Guernsey Mem'l Hosp.*, 514 U.S. at 99);

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[6] This Court has repeatedly found the Attorney General's 1947 Manual interpreting the APA to be a persuasive construction of the APA. See, *e.g.*, *Norton* v. *Southern Utah Wilderness Alliance*, 542 U.S. 55, 63-64 (2004) (citing cases); *Vermont Yankee Nuclear Power Corp.* v. *NRDC, Inc.*, 435 U.S. 519, 546 (1978).

accord 1947 APA Manual 30 n.3. Unlike "substantive" rules, "'interpretive rules' * * * do *not* have the force and effect of law," and courts are therefore not required to give them "the binding effect of law." *Chrysler Corp.*, 441 U.S at 302 n.31, 315 (citation omitted; emphasis added; citation omitted); accord *Mortgage Bankers Ass'n*, 135 S. Ct. at 1208; *Guernsey Mem'l Hosp.*, 514 U.S. at 99.

The APA had been in effect for some 40 years when Congress added the notice-and-comment requirement for Medicare rules that "establish[] or change[]" certain "substantive legal standard[s]." 42 U.S.C. 1395hh(a)(2); see Omnibus Budget Reconciliation Act of 1987 (1987 OBRA), Pub. L. No. 100-203, Tit. IV, Subtit. A, Pt. 2, Subpt. C, § 4035(b), 101 Stat. 1330-78. Against the longstanding and well settled backdrop of the APA's governing legal framework, including this Court's decision in *Chrysler Corp.*, Congress would have understood the "central distinction * * * in the APA * * * between 'substantive rules' on the one hand and 'interpretive rules' * * * on the other." 441 U.S. at 301 (citation omitted). And Congress likewise would have understood the "well established" principle that "substantive agency regulations" carry the "'force and effect of law,'" while "'interpretive rules' * * * do not." *Id.* at 295, 302 n.31 (quoting, *e.g.*, 1947 APA Manual 30 n.3).

Those principles are embodied in Congress's decision to apply Section 1395hh(a)(2) only to agency actions that "establish[] or change[]" certain "substantive legal standard[s]"—that is, to substantive rules. Indeed a quintessential function of a "*substantive* rule" is "to implement statutory policy" by "defining *standards*" that carry the "force and effect *of law*." 1947 APA Manual 13 n.5, 30 n.3 (emphases added). "[I]f a word is obviously transplanted from another legal source, whether

the common law or other legislation, it brings the old soil with it." *Sekhar* v. *United States*, 570 U.S. 729, 733 (2013) (quoting Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 Colum. L. Rev. 527, 537 (1947)). When Congress transplanted the words "substantive," "legal" (*i.e.*, "of law"), and "standard" from decades of APA jurisprudence to the Medicare Act, it brought along their established meaning: a substantive rule that has the force and effect of law.

Nothing in Section 1395hh suggests that Congress, in enacting that provision, intended to jettison decades of administrative law and fashion an unprecedented notice-and-comment requirement for interpretive rules or other interpretive actions by CMS in its administration of the vast and complex Medicare program. To the contrary, the function played by an interpretive rule is incompatible with the text of Section 1395hh(a)(2). An interpretive rule by its very nature does not "establish[] or change[]" a "substantive legal standard," 42 U.S.C. 1395hh(a)(2). Such a rule simply sets forth "the agency's *construction* of the statutes and rules which it administers." *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204 (emphasis added; citation omitted). The view that "an interpretive rule *changes* the [legal provision] it interprets" cannot be "reconcile[d] with the longstanding recognition that interpretive rules do *not* have the force and effect of law." *Id.* at 1208 (emphases added). It follows that by limiting its notice-and-comment requirement to "rule[s] * * * that establish[] or change[] a substantive legal standard," 42 U.S.C. 1395hh(a)(2), the Medicare Act necessarily excludes HHS's nonbinding interpretations of the Act from that requirement.

b. In reaching a contrary conclusion, the court of appeals overlooked these well-established principles of

administrative law—the "old soil"—and instead relied on the definition of "substantive law" in the 10th edition of *Black's Law Dictionary*. Pet. App. 13a-14a. Because that dictionary defines "substantive law" as "law that creates, defines, and regulates the rights, duties, and powers of parties," the court concluded that "substantive legal standard" includes a standard "that creates, defines, and regulates the rights, duties, and powers of parties." *Ibid.* (citation and internal quotation marks omitted). The court further concluded that the quoted definition encompassed the FY2012 Medicare fractions furnished by CMS to the private contractors here. The court's reasoning was erroneous.

As an initial matter, the definition the court of appeals quoted is consistent with the understanding of the term "substantive rule" as used in administrative law, insofar as it refers to *law* that itself establishes binding standards governing the "rights, duties, and powers of parties." Such "substantive law," however, does not include *interpretations* of already existing law, whether announced in the form of an interpretive rule or in the course of an agency adjudication.

In any event, the court of appeals relied on an inapposite definition given the context of this case. As noted, the question in this case turns on the "central distinction" in administrative law between "substantive rules" and "interpretive rules." *Chrysler Corp.*, 441 U.S. at 301. The court of appeals instead relied on a dictionary entry focusing on the distinction between "substantive law" and *procedural* law, as the "Cf." citation and illustrative quotation in the full entry make clear:

> **substantive law** (səb-stən-tiv). (18c) The part of the law that creates, defines, and regulates the rights, duties, and powers of parties. Cf. PROCEDURAL LAW.

> "So far as the administration of justice is concerned with the application of remedies to violated rights, we may say that the substantive law defines the remedy and the right, while the law of procedure defines the modes and conditions of the application of the one to the other." John Salmond, *Jurisprudence* 476 (Glanville L. Williams ed., 10th ed. 1947).

Black's Law Dictionary 1658 (10th ed. 2014); see Bryan A. Garner, *Garner's Dictionary of Legal Usage* 713-714 (3d ed. 2011) (making the same distinction). But it is the former distinction, not the latter, that is relevant to the disposition of this case.

Defining "substantive law" in contradistinction to "procedural law" might make sense in some other contexts—but it is inapt to the specialized distinction between "substantive rule" and "interpretive rule" germane to this case. See Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 418 (2012) ("you must use the context in which a given word appears to determine its aptest, most likely sense"). Understanding this specialized distinction requires specialized sources—here, the APA's text and structure, the Attorney General's 1947 APA Manual, and this Court's administrative law cases. As described above, those sources make clear that "interpretive rules"—ones that merely explain "'the agency's construction of the statutes and rules which it administers'" but "do not have the force and effect of law," *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204, 1208 (citation omitted)—are distinct from "substantive rules." Even the dictionary on which the court of appeals relied defines "substantive *rule*" (not "substantive law") by reference to "legislative rule," *Black's Law Dictionary*

1658 (emphasis added; capitalization altered), which in turn is defined as a rule having "the force of law" and is contradistinguished from an "interpretative rule," *id.* at 1040 (capitalization altered). By any relevant definition, therefore, the plain meaning of "rule, requirement, or other statement of policy * * * that establishes or changes a substantive legal standard" necessarily excludes interpretive rules. 42 U.S.C. 1395hh(a)(2). Subsection (a)(2) thus does not apply to interpretive rules, as three other courts of appeals have correctly held. *Baptist Health* v. *Thompson*, 458 F.3d 768, 776 & n.8 (8th Cir. 2006); *Erringer* v. *Thompson*, 371 F.3d 625, 632-633 (9th Cir. 2004); *Warder* v. *Shalala*, 149 F.3d 73, 79 & n.4 (1st Cir. 1998), cert. denied, 526 U.S. 1064 (1999).

Nor was the court of appeals correct to rely (Pet. App. 16a) on the fact that the Medicare Act expressly incorporates the APA's good-cause exception to notice-and-comment rulemaking, see 5 U.S.C. 553(b)(B), but not its exception for interpretive rules, see 5 U.S.C. 553(b)(A). 42 U.S.C. 1395hh(b)(2). The Medicare Act limits its notice-and-comment requirement to "rule[s] * * * that establish[] or change[] a substantive legal standard." 42 U.S.C. 1395hh(a)(2). There is thus no need for an express *exception* from that requirement for interpretive rules, because interpretive rules already are excluded from the scope of notice-and-comment rulemaking in the first place. An express good-cause exception, on the other hand, is necessary because it applies to substantive rules, which *are* covered by Section 1395hh(a)(2)—just as a good-cause exception is necessary for substantive rules under the APA too. Cf. *Reynolds* v. *United States*, 565 U.S. 432, 438 (2012); *Carr* v. *United States*, 560 U.S. 438, 444 n.2 (2010). So the Medicare Act's express incorporation of the APA's good-

cause exception, but not its interpretive-rule exception, does not imply that interpretive rules are subject to a notice-and-comment requirement. To the contrary, it reaffirms that interpretive rules are excluded from the notice-and-comment provision's scope to begin with.

Respondents' suggestion (Br. in Opp. 28-29) that 42 U.S.C. 1395hh(c) "cuts against" the government's reading of the statute also is mistaken. Subsection (c) commands the Secretary to "publish in the Federal Register" at least every three months "a list of all * * * interpretive rules * * * which * * * are not published pursuant to subsection (a)(1) of this section." 42 U.S.C. 1395hh(c)(1) and (B). "By requiring publication of a list of interpretive rules that have *not* gone through notice and comment," respondents assert, subsection (c) "presupposes that some interpretive rules *are* subject to section 1395hh(a)(2)'s notice-and-comment requirement." Br. in Opp. 28-29. Not so. Subsection (c) simply recognizes the possibility that the agency might in some instances *choose* to promulgate a regulation through notice-and-comment rulemaking embodying a statutory interpretation that would otherwise be issued in another form, such as in the Provider Reimbursement Manual. That is what HHS chose to do regarding its interpretation of the Medicare-fraction provision in 2004 and 2013. See 78 Fed. Reg. at 50,614-50,615; 69 Fed. Reg. at 49,099. In that event, the statute simply makes clear that the interpretive rule need not be published a second time in a quarterly list under subsection (c)(1); once is enough. 42 U.S.C. 1395hh(c)(1)(B). It does not imply that interpretive rules must go through notice-and-comment rulemaking.

2. The drafting history of Section 1395hh confirms that it does not apply to nonbinding interpretations of the Medicare Act

Section 1395hh(a)(2)'s drafting history confirms that Congress did not intend a "rule * * * that establishes or changes a substantive legal standard" to encompass an interpretive rule that by definition lacks binding legal force. 42 U.S.C. 1395hh(a)(2). After HHS had taken steps that called into question the continued applicability and enforceability of APA rulemaking procedures under the Medicare program, Congress enacted Section 1395hh's Medicare-specific rulemaking provisions to ensure that Medicare regulations that had long been governed by the APA's rulemaking process would continue to be promulgated through notice-and-comment rulemaking. In doing so, Congress adapted the APA's governing legal framework to the Medicare context.

a. The APA's rulemaking provisions do not apply to any "matter relating to * * * benefits." 5 U.S.C. 553(a)(2). Nevertheless, not long after Medicare's enactment, HHS's predecessor "determined, as a matter of policy, to abide by the APA's notice-and-comment requirements" in its various benefits programs anyway. *Lincoln* v. *Vigil*, 508 U.S. 182, 196 n.5 (1993). Accordingly, in 1971 the Secretary issued a statement of policy directing HHS "to utilize the public participation procedures of the APA." 36 Fed. Reg. 2532, 2532 (Feb. 5, 1971). Throughout the 1970s and into the 1980s, courts held that HHS and its predecessor were bound by that policy, which therefore required the agency to comply with the APA's notice-and-comment requirements, 5 U.S.C. 553(b) and (c). See *Clarian Health W., LLC* v. *Hargan*, 878 F.3d 346, 356-357 (D.C. Cir. 2017) (citing

cases); *Humana of S.C., Inc.* v. *Califano*, 590 F.2d 1070, 1082, 1084 & n.103 (D.C. Cir. 1978).

In 1982, however, HHS published a notice of proposed rulemaking that called into question HHS's continued commitment to conduct APA rulemaking under the Medicare program. See 47 Fed. Reg. at 26,860. The proposal explained that, as a matter of "policy," HHS would "ordinarily * * * use notice and comment procedures," "even though such action is not required by the [APA]" for "rules governing * * * Medicare" and other benefits programs. *Ibid.* Although the notice of proposed rulemaking stated that HHS would generally continue to apply APA rulemaking procedures to benefits programs, HHS could decline to do so if it concluded that the costs of the notice-and-comment process would "outweigh" its benefits in any particular instance. *Ibid.* The proposal further clarified that HHS's "voluntary" policy of conducting notice-and-comment rulemaking was not intended to "create any right or benefit enforceable at law." *Id.* at 26,860-26,861 (proposing 45 C.F.R. 2.2(c)). HHS's proposal "would have [had] the effect of rescinding" its 1971 policy, which courts had held to be judicially enforceable, of complying with APA notice-and-comment rulemaking requirements. See Office of the Chairman, Administrative Conference of the United States, *A Guide to Federal Agency Rulemaking* 27 n.44 (1983).

HHS's proposed rule was met with swift opposition. Less than two months after the published notice, Representative Weiss, joined by 53 of his colleagues, introduced a concurrent resolution resolving that HHS "should withdraw [these] proposed rules * * * that would reduce public notice and comment opportunities." H.R. Con. Res. 401, 97th Cong., 2d Sess. 2 (1982). HHS, the

concurrent resolution stated, "has successfully adhered to Administrative Procedure Act notice and comment period procedures for twelve years." *Ibid.* The agency should thus "affirm current practices." *Ibid.*

HHS never finalized its 1982 proposal, which over the next several years generated criticism from a "broad-based coalition" that expressly wanted HHS "to follow the procedures delineated in the APA (including notice of proposed rule-making) when issuing any regulation or rule relating to Medicare." *Medicare Appeals Provisions: Hearing on S. 1158 Before the Subcomm. on Health of the Senate Comm. on Finance*, 99th Cong., 1st Sess. 25-26 (1985).[7] According to these concerned parties, "the time ha[d] come to make it clear, *by statute*, that Medicare regulations * * * should be subject to the [APA]." *Id.* at 62.

b. In 1986 and 1987, rather than amend the APA to eliminate the exemption for "matter[s] relating to * * * benefits," 5 U.S.C. 553(a)(2), which would have extended to benefit programs generally, Congress prescribed notice-and-comment rulemaking only for the Medicare program, and did so in the Medicare Act itself. It did so

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[7] See, *e.g.*, *Social Security Disability Insurance Program: Hearing Before the Senate Comm. on Finance*, 97th Cong., 2d Sess. 462 (1982) (statement of National Senior Citizens Law Center); *Department of Health and Human Services Oversight: Hearing Before the House Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 97th Cong., 2d Sess. 91 (1982) (August 17, 1982 letter from House Committee Chairmen Dingell, Brooks, and Rodino); H.R. Con. Res. 19, 98th Cong., 1st Sess. (1983) (Rep. Weiss reintroducing his concurrent resolution); *Examination of Quality of Care Under Medicare's Prospective Payment System: Hearing Before the Senate Comm. on Finance*, 99th Cong., 2d Sess. 334, 346 (1986) (statement of American Association of Retired Persons).

by amending 42 U.S.C. 1395hh, which at the time simply authorized the Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [the Medicare Act]." 42 U.S.C. 1395hh (1982) (App., *infra*, 6a).

In 1986, Congress added Subsection (b) to Section 1395hh. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, Tit. IX, Subtit. D, Pt. 2, § 9321(e), 100 Stat. 2017-2018; see 42 U.S.C. 1395hh(b) (Supp. IV 1986) (App., *infra*, 7a). That provision, unchanged today, requires the Secretary to "provide for notice of [a] proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon"—twice the 30-day minimum in the APA, 5 U.S.C. 553(d)—"before issuing in final form any regulation under subsection (a)." 42 U.S.C. 1395hh(b)(1). It also exempts regulations from the 60-day notice-and-comment requirement where a statute permits otherwise, where a statute requires (relatively) fast implementation, or in circumstances where the APA's good-cause exception (5 U.S.C. 553(b)(B)) would apply. 42 U.S.C. 1395hh(b)(2). As amended, Section 1395hh did not expressly state which sorts of rulemaking would be covered by the notice-and-comment requirement. The Conference Report for the bill explained, however, that Section 1395hh(b) "does not require the Secretary to [follow notice-and-comment rulemaking] for items (such as interpretive rules * * *) that are not currently subject to that requirement." H.R. Conf. Rep. No. 1012, 99th Cong., 2d Sess. 311 (1986).

The following year, Congress enacted subsection (a)(2), the provision now at issue. 1987 OBRA § 4035(b), 101 Stat. 1330-78; see 42 U.S.C. 1395hh(a)(2) (1988) (App., *infra*, 8a). That provision, unchanged today, states that

"[n]o rule, requirement, or other statement of policy * * * that *establishes or changes* a *substantive legal standard* governing * * * the payment for services * * * under [the Medicare Act] shall take effect unless it is promulgated by the Secretary by regulation under [Section 1395hh(a)(1)]." 42 U.S.C. 1395hh(a)(2) (emphasis added).

The House of Representatives initially passed a version of what eventually became subsection (a)(2) in much broader form:

> No rule, requirement, or other statement of policy * * * that *has (or may have) a significant effect on* * * * the payment for services * * * under [the Medicare Act] shall take effect unless it is promulgated by the Secretary by regulation under [Section 1395hh(a)(1)].

133 Cong. Rec. 30,019 (1987) (emphasis added) (reproducing H.R. 3545, 100th Cong., 1st Sess. § 4073(a)(2) (1987)); *id.* at 30,237-30,238 (passage by House of Representatives); see H.R. Rep. No. 391, 100th Cong., 1st Sess. 594-595 (1987). The Senate bill contained no corresponding provision. H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. 565 (1987) (1987 Conf. Report).

The House and Senate conferees then amended the House provision by replacing the italicized language above with the phrase "establishes or changes a substantive legal standard governing." 1987 Conf. Report 82, 563. "[T]his language," the 1987 Conference Report explained, "reflect[ed] recent court rulings." *Id.* at 566. The amendment "clarif[ied] that only policies establishing or changing a substantive legal standard governing benefits, payment, or eligibility must be promulgated as *regulations*." *Ibid.* (emphasis added). The statutory text

and description in the 1987 Conference Report were consistent with the 1986 amendment, which subjected only "regulation[s]" to notice-and-comment requirements. 42 U.S.C. 1395hh(b)(1).

c. This statutory drafting history embodies three key lessons. First, the 1986 and 1987 amendments were enacted in response to the concerns of lawmakers and citizens who objected to HHS's 1982 proposal and who wanted HHS to comply with *the APA*—which they explicitly identified by name. Nothing in the drafting history so much as hints that Congress had some other, novel administrative rulemaking procedures in mind when it enacted Section 1395hh(a)(2). The most natural reading of that provision, especially when viewed in light of the legal landscape against which it was enacted, is that it simply imports APA principles into the Medicare Act. Under those APA principles, of course, interpretive rules—nonbinding agency interpretations of the statutes and regulations it administers—do not, by definition, "establish[] or change[] a substantive legal standard." 42 U.S.C. 1395hh(a)(2).

Second, Congress significantly narrowed the text of what became Section 1395hh(a)(2). As initially proposed, that provision would have covered rules that "may have" had (not actually have had) a "significant effect" (not a binding legal effect) on Medicare payments. 133 Cong. Rec. at 30,019. But Congress rejected that language. In particular, by restricting subsection (a)(2)'s scope to rules that actually "establish[] or change[] a substantive legal standard," 42 U.S.C. 1395hh(a)(2), Congress deliberately used language reflecting the well-settled administrative-law notice-and-comment framework that excludes interpretive rules, which by definition have no binding legal effect.

Third, the only "recent court rulings" on which Congress could have based Section 1395hh's "substantive legal standard" language were decisions interpreting *the APA*. After all, the APA was the only statute whose rulemaking requirements could have been enforced against the agency at the time.

One of the most significant then-recent court rulings was the D.C. Circuit's decision in *American Hospital Association* v. *Bowen*, 834 F.2d 1037 (1987). That case involved a legal challenge by an association of 6000 member hospitals to HHS's adoption, without notice-and-comment rulemaking, of certain directives, transmittals, and contracts concerning Peer Review Organizations (PROs) under the Medicare program. *Id.* at 1043. Like the private contractors here, PROs contracted with HHS to assist it in deciding "whether Medicare should pay for the services" provided by hospitals. *Id.* at 1042. The court of appeals concluded that the challenged provisions did not require notice-and-comment rulemaking because they had left "unchanged" the "substantive standard for reimbursement under the Medicare statute." *Id.* at 1055. The APA's notice-and-comment requirement, the court said, applies only to "'substantive rules'" that "'create law'" and "'establish[] a standard of conduct which has the force of law,'" and not to "[i]nterpretive rules" that "'merely clarify or explain existing law.'" *Id.* at 1045-1046 (citations omitted). The court made clear that notice-and-comment procedures *would* have been necessary had HHS imposed a "new standard" or "change[d] the standard" for reimbursement. *Id.* at 1051.

American Hospital Association, which applied well-settled principles of administrative law, thus forms the backdrop for the very language ("establishes or changes

a substantive legal standard") that Congress enacted to "reflect[] recent court rulings," 1987 Conf. Report 566. Other examples of then-recent decisions describing in similar terms the types of regulations for which the APA requires notice-and-comment include *National Latino Media Coalition* v. *FCC*, 816 F.2d 785, 788 (D.C. Cir. 1987) ("binding" rules that "make[] law"); *Mada-Luna* v. *Fitzpatrick*, 813 F.2d 1006, 1013-1014 (9th Cir. 1987) ("binding rule of substantive law") (citation omitted); and *Grumman Ohio Corp.* v. *Dole*, 776 F.2d 338, 351 (D.C. Cir. 1985) ("substantive legal effect") (citation omitted). That preexisting jurisprudence confirms that the phrase "changes a substantive legal standard" in Section 1395hh(a)(2) incorporates standard APA principles —and thus excludes from its scope an agency's nonbinding interpretation of the statutes it administers.

B. The Challenged Agency Action Here Is Based On A Nonbinding Interpretation Of The Medicare Act

1. CMS's calculation of respondents' FY2012 Medicare fractions did not "establish[] or change[]" a "substantive legal standard" under 42 U.S.C. 1395hh(a)(2) because it was based on the agency's nonbinding interpretation of the Medicare Act. That underlying statutory interpretation is, at most, an interpretive rule to which subsection (a)(2) does not apply. A rule is interpretive if it merely explains "'the agency's construction of the statutes and rules which it administers'" and "do[es] not have the force and effect of law." *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204, 1208 (citation omitted).

Both are true here. The agency determined that Part C patient days should be included in the Medicare fraction. That was simply a "construction of the statute[]." *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204 (citation omitted). The Medicare Act expressly requires

the fraction to include patient days of patients "entitled to benefits under part A." 42 U.S.C. 1395ww(d)(5)(F)(vi)(I). But the Act also expressly says that Part C patients *must* be "entitled to benefits under part A." 42 U.S.C. 1395w-21(a)(3)(A) (2012). Whether the phrase "entitled to benefits under part A" means the same thing in these two statutory provisions is a quintessential "construction of the statute[]" by the CMS Administrator.

The agency's inclusion of Part C patient days in the Medicare fractions furnished to its contractors also does not have the force and effect of law. Those fractions merely supply one aspect of the contractors' initial reimbursement determinations. Although the contractors, rather than fulltime CMS staff, make those reimbursement determinations, they do so as agents of CMS itself. 42 U.S.C. 1395kk-1(a)(1) and (4)(A). Their reimbursement determinations are therefore just the first step in CMS's own administrative adjudicatory process. Subject to an amount-in-controversy threshold, a hospital may appeal the reimbursement determination to the Provider Reimbursement Review Board. 42 U.S.C. 1395*oo*(f)(1). In that appeal, the contractor's determination of the hospital's total reimbursement (which includes the Medicare fraction, among other calculations) is not binding. Although the Board must apply the statute, regulations, and formal CMS Rulings, it need not follow the Provider Reimbursement Manual or other interpretive materials, including the Medicare fraction or the statutory interpretation on which it is based. 42 C.F.R. 405.1867. Nor are the fractions or reimbursement determinations binding on the CMS Administrator (acting for the Secretary) when she reviews the Board's decision, or on courts in subsequent judicial review. See 42 U.S.C. 1395*oo*(f)(1); 42 C.F.R. 405.1875. It

follows that the FY2012 Medicare fractions here are, at most, interpretive rules outside the scope of Section 1395hh's notice-and-comment requirements.

Indeed the agency's calculations of the FY2012 Medicare fractions based on its interpretation of the Medicare Act, and the contractors' subsequent calculations of respondents' reimbursement amounts, most resemble the reimbursement calculations at issue in *Guernsey Memorial Hospital*. As relevant here, the question in that case was whether an accounting provision in the Provider Reimbursement Manual that specified amortized, rather than immediate, reimbursement of certain provider costs had to be issued through notice-and-comment rulemaking. 514 U.S. at 90. Applying the APA (the 1985 cost year at issue predated the 1986 and 1987 amendments to Section 1395hh), the Court held that it did not. *Id.* at 100. The challenged provision in that case simply "implement[ed] [a] statutory" command. *Id.* at 98. In fact it was just "the first step toward reimbursement," not "the only step." *Id.* at 94. And the resulting calculations did "not have the force and effect of law * * * in the adjudicatory process." *Id.* at 99. Accordingly, this Court held that the challenged manual provision was "a prototypical example of an interpretive rule" that did "not require notice and comment" under APA standards. *Ibid.* Just so here.

2. In fact the challenged action here is not "a rule, requirement, or other statement of policy" to which subsection (a)(2) applies in the first place. 42 U.S.C. 1395hh(a)(2). The agency's calculation of respondents' FY2012 Medicare fractions is not a "rule," for it neither has "future effect" nor involves a "prescription for the future." 5 U.S.C. 551(4) (APA definition of "rule"). To the contrary, the agency in theory would remain free to

calculate the fractions in other years (between 2004 and 2013, at least, when no binding regulation was in effect) based on a different nonbinding interpretation of the statute, if it chose. And not even respondents claim that their FY2012 fractions are "statement[s] of policy."

That leaves "requirement." The court of appeals held that CMS's calculation of respondents' FY2012 Medicare fractions constituted a "'requirement'" to which Section 1395hh(a)(2) applies because the agency directed that its contractors "use [those] Medicare fractions in calculating adjustment amounts" and thereby "*required* [the contractors] to include Part C days in their calculations." Pet. App. 12a-13a. That reasoning is erroneous.

In context, "requirement" in subsection (a)(2) means a "requirement" for *providers*. It does not encompass instructions to the agency's own contractors making initial reimbursement determinations on CMS's behalf. Evaluating a similar challenge to CMS's instructions to its contractors, *American Hospital Association*—one of the "recent court rulings" that inspired Section 1395hh(a)(2), 1987 Conf. Report 566; see pp. 34, 36-37, *supra*—made clear that "[i]t is irrelevant whether an HHS directive * * * requir[es] [private entities], as a condition of entering into a contract with HHS," to follow the agency's instructions when they make determinations on the agency's behalf. 834 F.2d at 1049. Focusing, as the court of appeals in this case did, on the fact that private contractors are bound to follow CMS's instructions "fail[s] to take heed of the critical difference between [private contractors] and hospitals" in this context: namely, that contractors are acting *on behalf of the agency itself*. *Ibid.* In view of "Congress' expressed desire that HHS utilize private [entities]" to administer the Medicare program, HHS must be able to "reach

through its contracting agents the same result that it could surely reach itself by using its own employees." *Ibid.*; see 42 U.S.C. 1395kk-1(a)(1). The court of appeals' holding in this case contravenes these principles.

C. The D.C. Circuit's Interpretation of Section 1395hh Would Substantially Undermine HHS's Ability To Administer The Medicare Program

The court of appeals' interpretation of Section 1395hh, including its holding that CMS interpretive rules—such as the extensive and detailed provisions of the Provider Reimbursement Manual, including the one at issue in *Guernsey Memorial Hospital*—require notice-and-comment rulemaking, would substantially undermine HHS's ability to administer Medicare in a workable manner.

1. The Medicare program is a "massive, complex health and safety program * * * embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations." *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). In particular, those provisions setting forth the substantive legal standards for reimbursement routinely contain myriad ambiguities that must be resolved, at least as an initial matter, by CMS in its administration of the Medicare program. Agency interpretations such as those in the Provider Reimbursement Manual thus set forth CMS's views on questions of Medicare reimbursement for the benefit of providers and promote national uniformity in the administration of the Medicare program by guiding contractors in the initial reimbursement determinations they make on behalf of the agency. Such interpretations, which do not have the force and effect of law and thus are not legally binding on the Provider Reimburse-

ment Review Board or courts that review Medicare decisions, have long been held exempt from notice-and-comment rulemaking. See, *e.g.*, *Guernsey Mem'l Hosp.*, 514 U.S. at 90, 99.

The court of appeals' interpretation of Section 1395hh would substantially undermine this longstanding administrative framework. Converting the agency's nonbinding manuals and other interpretive materials into regulations requiring notice-and-comment rulemaking would jeopardize the flexibility that is essential in light of Medicare's complex and frequently changing statutory context and administrative developments. The notice-and-comment process can be "long and costly" and "often requires many years and tens of thousands of person hours to complete." Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretative Rules*, 52 Admin. L. Rev. 547, 550-551 (2000). To be sure, the agency might be able to promulgate *some* regulations relatively quickly. Cf. Br. in Opp. App. 1a-3a. But the court of appeals' rationale, if taken to its logical conclusion, would subject nearly *all* of CMS's nonbinding manuals and interpretive materials to the notice-and-comment process because the agency's contractors are "required to follow" *all* of those instructions when performing functions on behalf of CMS. 74 Fed. Reg. at 65,312. It is difficult even to estimate the disruptive effect that would have on the Medicare program.

2. The court of appeals reasoned that CMS's inclusion of Part C days in its calculation of respondents' FY2012 Medicare fractions "change[d] a substantive legal standard," 42 U.S.C. 1395hh(a)(2), and therefore required notice-and-comment rulemaking, because it reflected a "change from [the agency's] prior practice" of

"excluding Part C days from Medicare fractions." Pet. App. 13a. That reasoning is flawed.

If the agency's calculation of the FY2012 fractions was invalid because it "change[d]" a substantive legal standard without notice-and-comment rulemaking, then the agency's earlier, pre-2004 practice of excluding Part C days was *also* invalid because that practice "establishe[d] * * * [the] substantive legal standard," 42 U.S.C. 1395hh(a)(2), that the FY2012 fractions purportedly "changed." That cannot be right. Cf. *Mortgage Bankers Ass'n*, 135 S. Ct. at 1206 (notice-and-comment rulemaking not required under the APA to "change" an agency interpretive rule when the agency could establish the interpretive rule without notice and comment in the first place).

Yet under the D.C. Circuit's rationale, HHS could not now even follow its pre-2004 practice, because that practice would itself establish a "substantive legal standard" and thus could not "take effect" without notice-and-comment rulemaking. 42 U.S.C. 1395hh(a)(2) and (b)(1). And under that rationale, CMS could not have properly calculated *any* Medicare fractions for *any* hospital after the 1997 enactment of Medicare Part C, notwithstanding its continuing obligation to do so. Fulfilling that obligation required the private contractors to apply *some* interpretation of the statutory Medicare-fraction provision to decide whether to count Part C days, but no such interpretation could be applied, under the logic of the decision below, without notice-and-comment rulemaking. That anomalous result—which would prohibit the agency from taking the actions needed for the contractors to process annual Medicare reimbursement requests—further underscores the court of appeals' error here.

II. SECTION 1395hh(a)(4) DID NOT REQUIRE NOTICE-AND-COMMENT RULEMAKING FOR CMS TO FURNISH THE CHALLENGED INSTRUCTIONS TO ITS CONTRACTORS

A. Section 1395hh(a)(4) Did Not Provide An Independent Basis To Require Notice-And-Comment Rulemaking

If, as the government maintains, Section 1395hh(a)(2) did not require notice and comment under the circumstances of this case, Section 1395hh(a)(4) does not provide an independent basis to conclude otherwise. Subsection (a)(4) requires a "final regulation" to be "a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule." 42 U.S.C. 1395hh(a)(4). The "logical outgrowth" rule is a familiar one under the APA. See *Long Island Care at Home, Ltd.* v. *Coke*, 551 U.S. 158, 174-175 (2007). But unlike the APA, under which the "unlawfully promulgated regulation" ordinarily "can be left in place while the agency provides the proper procedural remedy," *Fertilizer Inst.* v. *EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991), subsection (a)(4) says that the procedurally defective regulation "shall be treated as a proposed regulation and shall not take effect" without a further notice-and-comment opportunity. 42 U.S.C. 1395hh(a)(4).

Importantly, a "regulation" under subsection (a)(4) is the same type of "regulation" described throughout Section 1395hh, namely, one "promulgated by the Secretary" under subsection (a)(1) that follows the procedural requirements (*i.e.*, notice and comment) described in subsection (b). 42 U.S.C. 1395hh(a)(1) and (b). And by its terms, subsection (a)(4) applies only "[i]f the Secretary publishes a final regulation." 42 U.S.C. 1395hh(a)(4). Subsection (a)(4) thus logically does not apply to agency actions that are *not* published as final regulations. So if subsection (a)(2)—the "substantive legal standard"

provision—does not require an agency action to be "promulgated by the Secretary by regulation under [subsection (a)(1)]," and in fact the agency action is *not* promulgated as a final regulation, subsection (a)(4) has no independent force. 42 U.S.C. 1395hh(a)(2). If a rule need not—and therefore does not—go through notice-and-comment rulemaking, it would be nonsensical to prevent the rule from "tak[ing] effect" under subsection (a)(4) unless it goes through notice-and-comment rulemaking. 42 U.S.C. 1395hh(a)(4). Accordingly, if subsection (a)(2) did not require notice and comment here, subsection (a)(4) does not provide an independent basis to conclude otherwise.

The court of appeals' theory (Pet. App. 17a-18a), echoed by respondents (Br. in Opp. 18-19), appears to be that because the *2004 regulation* was not a "logical outgrowth" of the 2003 proposed rule and thus did not "take effect," 42 U.S.C. 1395hh(a)(4), the agency's *2014 calculation* of respondents' FY2012 Medicare fractions also cannot take effect because it happens to be consistent with the 2004 rule. That reasoning is flawed for two reasons.

First, it overlooks key language in subsection (a)(4): a logical-outgrowth failure means the attempted "final regulation" "*shall be treated as a proposed regulation* and shall not take effect until" a further notice-and-comment period. 42 U.S.C. 1395hh(a)(4) (emphasis added). It would make no sense to "treat[]" CMS's 2014 calculation of respondents' FY2012 Medicare fractions—or the nonbinding statutory interpretation on which it was based—"as a proposed regulation" when the Secretary never attempted to propose it as a regulation in the first place. *Ibid.* And if subsection (a)(2) did not require the Secretary to propose it as a regulation, there is no basis to

conclude that subsection (a)(4) imposed a freestanding requirement to do so anyway.

Second, to the extent the court of appeals thought the 2014 calculation was itself an attempt to give "effect" to the unsuccessful 2004 regulation, it was mistaken. The FY2012 Medicare fractions were not based on the vacated 2004 regulation. The district court found "no convincing evidence that [the agency] relied on the vacated rule in promulgating the 2012" fractions. Pet. App. 31a; see also *id.* at 105a ("[Respondents'] posted 2012 SSI fractions were not calculated in reliance on the vacated rule."). Instead, CMS personnel "appropriately relied on and interpreted the underlying [Medicare] *statute* to calculate" the fractions. *Id.* at 31a (emphasis added). That determination was left undisturbed by the court of appeals, and was unchallenged by respondents in their brief in opposition in this Court. Because the 2012 fractions were not calculated based on the 2004 regulation, they did not give "effect" to that regulation, and subsection (a)(4) is thus inapplicable here.

B. Even If Section 1395hh(a)(4) Had Some Independent Force, It Did Not Apply Here Because The Agency Chose To Proceed By Adjudication

Even if Section 1395hh(a)(4) carried independent force, it would not apply here because the calculation of respondents' FY2012 Medicare fractions, in the absence of a governing regulation, represents the agency's choice to proceed by adjudication rather than by rulemaking. The court of appeals mistakenly rejected this position, reasoning that the agency "could not circumvent [subsection (a)(4)'s] requirement by claiming that it was acting by way of adjudication rather than rulemaking." Pet. App. 18a. But an agency does not "circumvent"

rulemaking when it chooses to proceed by an entirely lawful adjudicative process instead.

Agencies are generally free to choose between rulemaking and adjudication. *SEC* v. *Chenery Corp.*, 332 U.S. 194 (1947). That is true for HHS, too: although the APA exempts "matter[s] relating to * * * benefits" from its rulemaking provision, 5 U.S.C. 553(a)(2)—a gap that 42 U.S.C. 1395hh fills—it contains no prohibition against proceeding by adjudication to establish the amount of reimbursement to be paid to a hospital under Medicare. See *Guernsey Mem'l Hosp.*, 514 U.S. at 96-97. Acting by adjudication, rather than rulemaking, thus does not "circumvent" rulemaking procedures as a matter of law. *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). To be sure, rulemaking in this context might be appropriate to the extent the agency seeks to apply a similar formula to the adjudication of every hospital's ultimate reimbursement calculation on a more permanent basis. Cf. *Heckler* v. *Campbell*, 461 U.S. 458 (1983). But the agency "is not precluded from announcing new principles in an adjudicative proceeding" if it wishes to proceed in that manner instead. *Bell Aerospace*, 416 U.S. at 294.

That is particularly true when, as here, the agency *must* act whether or not a regulation is in place. Once the 2004 rule was set aside, there was no binding agency regulation addressing how to handle Part C patients in the Medicare fraction calculations. Yet HHS still "had a statutory duty to decide the issue at hand," *Bell Aerospace*, 416 U.S. at 292; for under the Medicare Act, "the Secretary *shall* provide * * * for an additional payment" to hospitals using the statutorily defined Medicare fraction, 42 U.S.C. 1395ww(d)(5)(F)(i) (emphasis added); see *Murphy* v. *Smith*, 138 S. Ct. 784, 787 (2018) ("the word 'shall' usually creates a mandate, not

a liberty"). And "this duty remained 'regardless of whether th[e] [Medicare fraction formula] previously had been spelled out in a general rule or regulation.'" *Bell Aerospace*, 416 U.S. at 292 (quoting *Chenery*, 332 U.S. at 201). Once the 2004 rule had been vacated, leaving nothing in its place, HHS had little choice but to address the handling of Part C patients by adjudication. See *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 14 (D.C. Cir. 2011) ("Prior to 2004, the regulation did not specify where [Part C] enrollees should be counted.").

It is no answer (cf. Br. in Opp. 31) that the 1986 interim final rule remained in effect. See p. 7, *supra*. That rule did not address how to handle Part C patients in the Medicare fraction; it could not have done so because Part C was not enacted until 1997. All the interim rule did was set forth the mechanical calculation the agency would undertake to determine a hospital's Medicare fraction: "The number of patient days of those patients entitled to both Medicare Part A and SSI will be determined by matching data [from two databases]." 51 Fed. Reg. at 16,777. Based on that match, "if a Medicare beneficiary is eligible for SSI benefits * * * during a month in which the beneficiary is a patient in the hospital, the *covered* Medicare Part A inpatient days of hospitalization in that month will be counted" in the Medicare fraction. *Ibid.* (emphasis added). Respondents latch onto the word "covered" to suggest that "only days covered and paid under part A were to be treated as part-A-entitled" under the interim rule, and therefore HMO or Part C patient days are excluded. Br. in Opp. 31. But in fact "covered" simply indicates that the days of patients who had *exhausted* their Medicare coverage for an inpatient stay would be excluded from the Medicare fraction. See 42 U.S.C. 1395d(a) and (b); *Catholic*

Health Initiatives Iowa Corp. v. *Sebelius*, 718 F.3d 914, 921 & n.5 (D.C. Cir. 2013). It does not mean that *covered* HMO (or Part C) patient days would also be excluded. Nor did the interim rule even purport to address the question of whether such patients are "entitled to benefits under part A."

By contrast, the agency did address that question in issuing the 1990 final rule on HMO patient days. In a precursor to Part C, the Medicare Act allowed certain individuals "entitled to benefits under part A" to enroll in a qualifying HMO plan and have their healthcare provided by the HMO. 42 U.S.C. 1395mm. HHS made clear in promulgating the 1990 regulation that patient days for those patients *would* be included in the Medicare fraction because, under the statute's plain text, they were "entitled to benefits under Part A." 55 Fed. Reg. at 35,994 (citing 42 U.S.C. 1395ww(d)(5)(F)(vi)). Those HMO patients are obviously quite analogous to Part C patients. Although the benefits of both are administered under provisions outside of Part A, both must be "entitled to benefits under part A," and the covered inpatient benefits of both are paid from the Part A Trust Fund. Compare 42 U.S.C. 1395mm(a) and (d), with 42 U.S.C. 1395w-21(a)(3)(A) (2012) and 42 U.S.C. 1395w-23(f). So if anything, it is the promulgation of the 1990 final rule—and not the earlier interim rule—that would provide the background rule in effect before the 2004 rulemaking attempt. The agency's choice to proceed by adjudication in a manner consistent with the 1990 rule thus did not circumvent any operative regulation at all.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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APPENDIX

1. 5 U.S.C. 551 provides in pertinent part:

Definitions

For the purposes of this subchapter—

* * * * *

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing;

(5) "rule making" means agency process for formulating, amending, or repealing a rule;

(6) "order" means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

(7) "adjudication" means agency process for the formulation of an order;

* * * * *

2. 5 U.S.C. 553 provides:

Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and

public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

3. 42 U.S.C. 1395w-21 (2012) provides in pertinent part:

Eligibility, election, and enrollment

(a) Choice of medicare benefits through Medicare+Choice plans

(1) In general

Subject to the provisions of this section, each Medicare+Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits (other than qualified prescription drug benefits) under this subchapter—

(A) through the original medicare fee-for-service program under parts A and B of this subchapter, or

(B) through enrollment in a Medicare+Choice plan under this part,

and may elect qualified prescription drug coverage in accordance with section 1395w-101 of this title.

(2) Types of Medicare+Choice plans that may be available

A Medicare+Choice plan may be any of the following types of plans of health insurance:

(A) Coordinated care plans (including regional plans)

(i) In general

Coordinated care plans which provide health care services, including but not limited to health maintenance organization plans (with or without point of service options), plans offered by

provider-sponsored organizations (as defined in section 1395w–25(d) of this title), and regional or local preferred provider organization plans (including MA regional plans).

(ii) Specialized MA plans for special needs individuals

Specialized MA plans for special needs individuals (as defined in section 1395w-28(b)(6) of this title) may be any type of coordinated care plan.

(B) Combination of MSA plan and contributions to Medicare+Choice MSA

An MSA plan, as defined in section 1395w-28(b)(3) of this title, and a contribution into a Medicare+Choice medical savings account (MSA).

(C) Private fee-for-service plans

A Medicare+Choice private fee-for-service plan, as defined in section 1395w-28(b)(2) of this title.

(3) Medicare+Choice eligible individual

(A) In general

In this subchapter, subject to subparagraph (B), the term "Medicare+Choice eligible individual" means an individual who is entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter.

(B) Special rule for end-stage renal disease

Such term shall not include an individual medically determined to have end-stage renal disease, except that—

(i) an individual who develops end-stage renal disease while enrolled in a Medicare+Choice plan may continue to be enrolled in that plan; and

(ii) in the case of such an individual who is enrolled in a Medicare+Choice plan under clause (i) (or subsequently under this clause), if the enrollment is discontinued under circumstances described in subsection (e)(4)(A) of this section, then the individual will be treated as a "Medicare+Choice eligible individual" for purposes of electing to continue enrollment in another Medicare+Choice plan.

* * * * *

4. 42 U.S.C. 1395hh (1982) provides:

Regulations

The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

5. 42 U.S.C. 1395hh (Supp. IV 1986) provides:

Regulations

(a) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means,

unless the context otherwise requires, regulations prescribed by the Secretary.

(b)(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

6. 42 U.S.C. 1395hh (1988) provides:

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list

of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which—

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this subchapter shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1395h of this title as are necessary to make easily accessible for the Secretary and other appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this subchapter, including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.

7. 42 U.S.C. 1395hh provides:

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice

of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which—

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this subchapter shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1395h of this title as are necessary to make easily accessible for the Secretary and other appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this subchapter, including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.

(e)[1] Retroactivity of substantive changes; reliance upon written guidance

(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

(i) such retroactive application is necessary to comply with statutory requirements; or

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[1] So in original. No subsec. (d) has been enacted.

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

(2)(A) If—

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1395zz(g) of this title) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any penalty or interest under this subchapter or the provisions of subchapter XI of this chapter insofar as they relate to this subchapter (including interest under a repayment plan under section 1395ddd of this title or otherwise) relating to the provision of such items or service or such claim if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.

(f) **Report on areas of inconsistency or conflict**

(1) Not later than 2 years after December 8, 2003, and every 3 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this subchapter and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect—

(A) Information from individuals entitled to benefits under part A or enrolled under part B of this subchapter, or both, providers of services, and suppliers and from the Medicare Beneficiary Om-

budsman with respect to such areas of inconsistency and conflict; and

(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

8. 42 U.S.C. 1395ww provides in pertinent part:

Payments to hospitals for inpatient hospital services

* * * * *

(d) **Inpatient hospital service payments on basis of prospective rates; Medicare Geographical Classification Review Board**

* * * * *

(5)(A)(i)

* * * * *

(F)(i) Subject to subsection (r), for discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which—

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this subchapter or State plans approved under subchapter XIX of this chapter), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

* * * * *

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds—

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of—

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter and were entitled to supplementary security income benefits (excluding any State supplementation) under subchapter XVI of this chapter, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX of this chapter, but who were not entitled to benefits under part A of this subchapter, and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of

patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under subchapter XI.

* * * * *

9. 42 C.F.R. 412.106 (2003)[1] provides in pertinent part:

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of covered patient days that—

(A) Are associated with discharges occurring during each month; and

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[1] The version of this provision reproduced in the Petition Appendix contained a typographical error.

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of patient days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible fo. Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * * *

10. 42 C.F.R. 412.106 (2004) provides in pertinent part:

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of patient days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * * *

11. 42 C.F.R. 412.106 provides in pertinent part:

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) *Determination of a hospital's disproportionate patient percentage*—(1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A (including Medicare Advantage (Part C)) and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A (including Medicare Advantage (Part C)).

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient

days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(iv) For cost reporting periods beginning on or after October 1, 2009, the hospital must report the days in the numerator of the fraction in the second computation in a cost reporting period based on the date of discharge, the date of admission, or the dates of service. If a hospital seeks to change its methodology for reporting days in the numerator of the fraction in the second computation, the hospital must notify CMS, through its fiscal intermediary or MAC, in writing at least 30 days before the beginning of the cost reporting period in which the change would apply. The written

notification must specify the methodology the hospital will use, the cost reporting period to which the requested change would apply, and the current methodology being used. Such a change will be effective only on the first day of a cost reporting period. If a hospital changes its methodology for reporting such days, CMS or the fiscal intermediary or MAC may adjust the number of days reported for a cost reporting period if it determines that any of those days have been counted in a prior cost reporting period.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * * *

No. 17-1484

In The Supreme Court of the United States

ALEX M. AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

ALLINA HEALTH SERVICES, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF FOR RESPONDENTS ALLINA HEALTH SERVICES ET AL.

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QUESTION PRESENTED

This case concerns the decision by the Department of Health and Human Services to forgo notice-and-comment rulemaking in a unique circumstance: when readopting a change in a substantive legal standard governing Medicare payment to hospitals nationwide after a notice-and-comment rule attempting to adopt the same change was vacated for a logical-outgrowth failure. That change, which the Government incorrectly dismisses as "contractor instructions," would deprive hospitals of billions of dollars in Medicare payments for past services to low-income patients.

The question presented is:

Whether 42 U.S.C. § 1395hh(a)(2) or § 1395hh(a)(4) required the Department of Health and Human Services to conduct notice-and-comment rulemaking before providing the challenged instructions to a Medicare Administrative Contractor making initial determinations of payments due under Medicare.

PARTIES TO THE PROCEEDING

Respondents are the private non-profit organizations identified below, who were plaintiffs in the district court and appellants in the court of appeals:

1. Allina Health System d/b/a Abbott Northwestern Hospital

2. Allina Health System d/b/a United Hospital

3. Allina Health System d/b/a Unity Hospital

4. Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital

5. Montefiore Medical Center

6. Mount Sinai Medical Center of Florida, Inc. d/b/a Mount Sinai Medical Center

7. New York - Presbyterian / Queens

8. New York Presbyterian Brooklyn Methodist Hospital

9. The New York and Presbyterian Hospital

Petitioner Alex M. Azar, II, Secretary of Health and Human Services, was defendant in the district court and appellee in the court of appeals.

RULE 29.6 DISCLOSURE

There are no parent companies, and no publicly held corporation owns 10 percent or more of any respondent's stock.

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RELEVANT STATUTORY AND REGULATORY PROVISIONS

The relevant statutory and regulatory provisions are reproduced in an addendum to this brief. Add. 1a-30a.

INTRODUCTION

In 2004, via notice-and-comment rulemaking, the Secretary of Health and Human Services ("HHS") attempted to change the standard governing Medicare payment for services furnished to low-income patients by hospitals nationwide. The agency botched that rulemaking: the final rule (ignoring its fiscal impact) was not the "logical outgrowth" of the proposed rule, and the D.C. Circuit vacated it. Days later, the agency attempted to make the same change, this time *without* undertaking any notice and comment. That renewed

attempt—the focus of this case—fails as well because two subsections of the Medicare Act, Sections 1395hh(a)(2) and 1395hh(a)(4), independently require the agency to engage in notice-and-comment rulemaking before the change can take effect.

The Government's effort to revive the faulty 2004 about-face without notice and comment relies on arguments that find no support in the text, structure, or purpose of the Medicare Act's special notice-and-comment requirements. Instead of applying the plain terms of Sections 1395hh(a)(2) and 1395hh(a)(4), the Government seeks shelter under "principles" of the Administrative Procedure Act ("APA"). But by conflating the two statutes, the Government ignores critical distinctions between them. Those distinctions include the Medicare Act's express recognition that a policy statement (which is not binding or subject to notice and comment under the APA framework), requirement (not mentioned in the APA), or rule (of any type) is capable of triggering the notice-and-comment mandate if it has the requisite substantive effect. The differences also include the Medicare Act's selective incorporation of the APA's explicit good-cause exemption but not its explicit interpretive-rule exemption. The Government's contorted attempt to conjure up an interpretive-rule-like exemption reads key terms out of the Medicare Act, and stands on unfounded speculation about the legal landscape and legislative history.

As the D.C. Circuit concluded, the agency cannot evade the specific notice-and-comment requirements Congress enshrined in the Medicare Act when altering

a substantive legal standard that reduces payments to hospitals—to the tune of billions of dollars. This Court should affirm.

STATEMENT OF THE CASE

I. MEDICARE PROGRAM

A. Special Notice-And-Comment Rulemaking Requirements

The federal Medicare program furnishes health-insurance benefits to elderly and disabled individuals. When it first enacted the Medicare program in 1965, Congress gave the agency general authority to prescribe regulations for administering the program. Social Security Amendments of 1965, Pub. L. No. 89-97, Title I, § 102(a), 79 Stat. 286, 331 (codified at 42 U.S.C. § 1395hh(a)(1)). Congress did not specify at that time whether those regulations required notice-and-comment rulemaking, or when Medicare policies required promulgation by regulation.

In 1971, the agency announced a policy of following the APA's notice-and-comment procedures for rules relating to Medicare benefits. Although the APA exempts rules related to "benefits" from its notice-and-comment requirements, 5 U.S.C. § 553(a)(2), the agency stated that it would engage in notice-and-comment rulemaking even "where not required by law." 36 Fed. Reg. 2,531, 2,532 (Feb. 5, 1971) (stating the agency would "utilize the public participation procedures of the APA" in issuing "rules and regulations relating to *** benefits").

In the early 1980s, Congress "fundamentally overhauled the Medicare reimbursement methodology," beginning with inpatient hospital care. *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1008 (D.C. Cir. 1999). Instead of reimbursing hospitals for the "reasonable costs" of inpatient care, Medicare began "reimburs[ing] qualifying hospitals at prospectively fixed rates" set annually each year by categories of patient diagnoses. *Id.* Thereafter, Congress made several amendments to the procedures required for promulgating Medicare policies, including for that prospective payment rate setting.

In 1986, Congress mandated for the first time that the agency follow notice-and-comment procedures, and articulated some requirements different from those under the APA. Specifically, Congress required a 60-day notice-and-comment period for Medicare regulations subject to three limited exceptions. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9321(e)(1), 100 Stat. 1874, 2017 (codified at 42 U.S.C. §§ 1395hh(a)(1), 1395hh(b)). The exceptions are: (1) where a statute specifically permits no prior public comment or a shorter comment period; (2) where a statute specifies a rulemaking deadline that falls within 150 days of its enactment; or (3) where the APA's "good cause" exemption (5 U.S.C § 553(b)(B)) is satisfied. 42 U.S.C. § 1395hh(b).

A year later, still concerned that "important policies [were] being developed without benefit of the public notice and comment period," H.R. REP. NO. 100-391(I), at 430 (1987), Congress further amended the Medicare statute to specify the kinds of policy changes

that require adoption by regulation after notice and comment. Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4035, 101 Stat. 1330, 1330-78. Pursuant to those amendments, the statute now mandates:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation [through notice-and-comment rulemaking].

42 U.S.C. § 1395hh(a)(2); *see also id.* § 1395hh(a)(1) (defining agency's authority to prescribe regulations); *id.* § 1395hh(b)(1) (requiring notice and comment before issuing any regulation under subsection (a)).

When it adopted that language in 1987, Congress went a step further to ensure advance notice of Medicare policy changes. When "manual instructions, interpretative rules, statements of policy, and guidelines of general applicability" are *not* required to be promulgated by notice and comment, Congress nonetheless required them to be published on a list in the Federal Register. Omnibus Budget Reconciliation Act of 1987, § 4035 (codified at 42 U.S.C. § 1395hh(c)(1)).

In 2003, Congress further modified the Medicare Act, again insisting on notice-and-comment rulemaking in circumstances where the APA does not require it:

> If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 902, 117 Stat. 2066, 2375 (codified at 42 U.S.C. § 1395hh(a)(4)).

At the same time, Congress addressed the retroactive application of substantive Medicare policy. It mandated that a "substantive change" made in any of several forms of administrative issuances—whether in "regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability"—"shall not be applied *** retroactively to items and services furnished before the effective date of the change," except under circumstances not applicable here. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 903 (codified at 42 U.S.C. § 1395hh(e)(1)(A)). It also provides that "no action shall be taken against a provider of services or supplier with respect to non-

compliance with such a substantive change." 42 U.S.C. § 1395hh(e)(1)(C).

B. Part A Fee-For-Service And Part C Managed Care Programs

Under Medicare Part A, the Government makes direct payments to hospitals for inpatient hospital services on a fee-for-service basis. 42 U.S.C. § 1395ww(d); *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011). The standard per-patient-discharge rates at which hospitals are paid are predetermined, but subject to further adjustments to account for factors that may cause a hospital to incur greater-than-average costs, such as the treatment of a high number of low-income patients. 42 U.S.C. § 1395ww(d)(5).

The agency undertakes yearly notice-and-comment rulemaking on changes to the Part A prospective payment rates and related adjustments. 42 U.S.C. § 1395ww(d)(6) (requiring agency to publish an annual update of the methodology and payment rates by August 1); 42 C.F.R. § 412.8 (same). That annual rulemaking takes an average of 102 days to complete. Br. in Opp'n App. 1a-3a.

Medicare administrative contractors (formerly called "fiscal intermediaries") perform Part A payment functions on behalf of the agency. Pet. App. 3a. A hospital must file an annual "cost report" with the Medicare contractor. 42 C.F.R. §§ 413.20, 413.24. The contractor then issues a notice of the final amount of Medicare program reimbursement due the hospital for that period (called an "NPR"). 42 C.F.R. §§ 405.1803, 405.1807.

If amount-in-controversy and other requirements are satisfied, a hospital may appeal that final determination, or the contractor's failure to issue a timely final determination, to the Provider Reimbursement Review Board ("Board")—an administrative tribunal appointed by the Secretary. 42 U.S.C. § 1395oo(a)(1), (h); 42 C.F.R. §§ 405.1835-405.1877. When the Board determines that it lacks authority to decide a question of law or regulations relevant to an appeal, hospitals have the right to immediate judicial review of the underlying agency decision. 42 U.S.C. § 1395oo(f)(1).

In 1997, Congress created Medicare Part C, currently called "Medicare Advantage" and formerly known as "Medicare+Choice" or "M+C." Part C established a managed care program that is an alternative to the Part A fee-for-service program. 42 U.S.C. § 1395w-21(a). An eligible beneficiary can elect to receive benefits through enrollment in a managed care plan under Part C in lieu of benefits under Part A. *Id.* § 1395w-21(a)(1), (i)(1); *see Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 6 (D.C. Cir. 2011).

II. THE AGENCY'S NEW STANDARD ON PART-A-ENTITLED DAYS IN THE DSH PAYMENT

A. The Part A DSH Payment Until 2004

As described above, the Medicare Part A rates paid to hospitals are subject to adjustments that account for factors causing a hospital to incur greater-than-average costs. One such adjustment is the "disproportionate share hospital" ("DSH") payment, which compensates hospitals for the additional costs

of providing services to low-income patients. 42 U.S.C. § 1395ww(d)(5)(F). The DSH payment turns on a "disproportionate patient percentage" that is the sum of two fractions representing inpatient care furnished to low-income individuals. *Id.* § 1395ww(d)(5)(F)(v), (vi). The two fractions depend, in inverse fashion, on the number of days spent in the hospital by patients who are "entitled to benefits under [Medicare] Part A." *Id.* § 1395ww(d)(5)(F)(vi)(I)-(II).

The first fraction, which the D.C. Circuit called the "Medicare fraction,"[1] measures the proportion of all hospital patients "entitled to benefits under [Medicare] Part A" (the denominator) who are also "entitled to supplementary security income [("SSI")] benefits" (the numerator). 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I). The agency determines and issues Medicare fractions for each federal fiscal year for all hospitals nationwide. Those fractions are binding on the agency when it issues final determinations of program reimbursement through its contractors, and on the hospitals for purposes of making claims for that reimbursement through cost reports. *See* 42 C.F.R. § 412.106(b)(2), (5); Pet. App. 12a.

The second fraction, the "Medicaid" fraction, measures the proportion of the total of all hospital patients (the denominator) who were Medicaid-

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[1] Respondents use this more general term for the Court's convenience, but under the statute, the fraction does not include all Medicare patient days, just those for patients entitled to Part A benefits. 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I).

eligible but "not entitled to benefits under Part A" (the numerator). 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II). The Medicaid fraction is determined by the Medicare contractor based on data furnished by the hospital in its cost report. 42 C.F.R. § 412.106(b)(4); 78 Fed. Reg. 50,496, 50,642 (Aug. 19, 2013).

Patients are either Part A entitled or not. Accordingly, a given patient can be counted in the numerator of one DSH fraction or the other, but not both. *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1108 (D.C. Cir. 2014) (*"Allina I"*).

To implement the DSH payment adjustment, including the determination of days in the DSH fractions, the agency has repeatedly used notice-and-comment rulemaking. *See* Br. in Opp'n App. 4a-6a. This includes at least six rulemakings to determine whether patient days not covered or paid under Medicare Part A are Part-A-entitled days, and ten other rulemakings to make changes to the treatment of other categories of days in the DSH payment. *See id.*

Before 2004, the agency considered Part C patients *not* entitled to benefits under Part A in calculating the DSH payment. *See* Pet. App. 4a ("Before 2004, HHS had *not* treated Part C enrollees as 'entitled to benefits under Part A.'") (citation omitted); *Allina I*, 746 F.3d at 1106, 1108 (agency "treated Part C patients as *not* entitled to benefits under Part A," "excluding Part C days from the Medicare fraction and including them in the Medicaid fraction") (citation omitted); *Northeast Hosp.*, 657 F.3d at 16-17 (2004 rule "contradicts [the agency's] former

practice of excluding [Part C] days from the Medicare fraction" as well as "longstanding" policy).

That approach reflected the original 1986 DSH regulation, which included as Medicare Part A entitled only patient days that were covered and paid under the Part A fee-for-service system. *See* 42 C.F.R. § 412.106(b)(2)(i) (2003) (defining Medicare fraction to include only "the number of *covered* patient days") (emphasis added); *see also id.* § 409.3 (defining "covered" as services for which payment is authorized); 51 Fed. Reg. 16,772, 16,777 (May 6, 1986) (explaining the Secretary's intent when regulation adopted to include only "covered Medicare Part A inpatient days"). Although the 1986 regulation did not expressly mention Part C patient days (as noted above, Part C came later), it necessarily excluded them as days not covered and paid under Part A. *See Catholic Health Initiatives Iowa Corp. v. Sebelius*, 718 F.3d 914, 921 n.5 (D.C. Cir. 2013) (noting that the pre-2004 regulation limited the Medicare fraction to "covered Medicare Part A inpatient days").

B. DSH Payment Changes Relating To Part C Patients

In 2003, the agency published a proposed rule "to clarify" that Part C days are excluded from Part-A-entitled days in the DSH fractions because they are not considered covered and paid under Part A. 68 Fed. Reg. 27,154, 27,208 (May 19, 2003). As the agency explained, "once a beneficiary has elected to join [a Part C] plan, that beneficiary's benefits are no longer administered under Part A." *Id.*; *see Allina I*, 746 F.3d at 1106.

In a final rule published in August 2004, however, the agency engaged in a "volte-face." *Allina I*, 746 F.3d at 1109. It adopted the exact opposite standard: counting days not paid by Part A, including Part C days, as Part-A-entitled days in the DSH calculation. 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004); *see also Allina Health Servs. v. Sebelius*, 904 F. Supp. 2d 75, 81 (D.D.C. 2012), *aff'd in part and rev'd in part*, 746 F.3d 1102 (D.C. Cir. 2014). Unlike the proposed rule, the final rule deleted the requirement that days must be "covered" by Medicare Part A to be included as Part-A-entitled days. *Compare* 42 C.F.R. § 412.106(b)(2)(i) (2003) *with* § 412.106(b)(2)(i) (2004); *see also* 69 Fed. Reg. at 49,246. The agency's only explanation for the about-face was that Part C patients "are still, in some sense, entitled to benefits under Medicare Part A." 69 Fed. Reg. at 49,099. In an impact analysis accompanying the 2004 final rule, the agency predicted that the Part C days change would not "have a significant impact on payments." 69 Fed. Reg. at 49,770.

In 2007, without providing notice or the opportunity for comment, the agency further amended the text of the DSH regulation governing Part C days to conform to the 2004 "policy change." 72 Fed. Reg. 47,130, 47,384 (Aug. 22, 2007). The agency framed the action as a "technical correction." *Id.*; *see Northeast Hosp.*, 657 F.3d at 14 n.8 ("Because of a clerical error, the text of § 412.106 was not actually revised until 2007."). Following that amendment, the regulation provided that the Medicare fraction would include (and Medicaid fraction would exclude) not just "covered" Part A patient days, but all days for

"patients entitled to benefits under Medicare Part A [(or Medicare Advantage (Part C))]." 72 Fed. Reg. at 47,383-84 (amending 42 C.F.R. § 412.106(b)(2)(i)(B) and (iii)(B)).

C. Challenges To The 2004 Rule (*Northeast Hospital* And *Allina I*)

The agency initially attempted to apply the new 2004 rule to DSH payments for services rendered in prior years. The D.C. Circuit rejected that maneuver, finding the rule "change[d] the legal consequences of treating low-income patients" and thus could not be applied retroactively. *Northeast Hosp.*, 657 F.3d at 13-17.[2]

Although the agency contended that the 2004 rule "codified a longstanding policy," the D.C. Circuit found that its "treatment of M+C days prior to 2004 *** belie[d] [that] claim." *Id.* at 15. Rejecting the agency's reliance on a 1990 rule concerning patient days paid through other health maintenance organizations ("HMOs"), the court noted that the 1990 rule did not actually address the Part C program and was contradicted by the agency's practice and written guidance regarding Part C days. *Id.* at 15-16. The

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[2] The hospitals there also argued that the 2004 rule was inconsistent with the DSH statute's plain terms. A divided panel disagreed, holding that the statute "has not clearly foreclosed the Secretary's interpretation" but "has left a statutory gap *** for the Secretary *** to fill." *Northeast Hosp.*, 657 F.3d at 13. Concurring in the judgment, then-Judge Kavanaugh agreed with the hospitals that a patient who "receives Medicare benefits under Medicare Part C for a particular 'patient day'" is not "also 'entitled' for that same 'patient day' to Medicare benefits under Medicare Part A." *Id.* at 18.

D.C. Circuit also rejected the Secretary's contention that her decision not to count Part C days as Part A entitled prior to implementing the 2004 rule was a "result of data system errors." *Id.* at 16. The court found that argument "not convincing" given the agency's pre-2004 written guidance, its contemporaneous description of the 2004 rule as newly "'adopting a policy' of counting [Part C] M + C days in the Medicare fraction," and its 2007 description of the 2004 rule as announcing a "policy change." *Id.* at 15-16.

In 2009, while that initial case challenging the retroactive application of the 2004 rule was pending, the agency began to apply the 2004 rule to later years, beginning with Medicare fractions for 2007. It was not until then that hospitals across the country began to understand the financial implications of the rule change. *See Allina I*, 746 F.3d at 1107 ("When the Secretary, in 2009, published reimbursement calculations for FY 2007 ***, the petitioners learned that their payments would decrease by tens of millions of dollars per year.").

A group of hospitals, including Respondents, brought a challenge (the precursor to this case) alleging that the 2004 rule changing the Part C days policy was not the "logical outgrowth" of the 2003

proposed rule "clarifying" the agency's former policy.[3] *Allina I*, 904 F. Supp. 2d at 89. The hospitals also argued that the rule was arbitrary and capricious because the agency's "cursory explanation in the 2004 Final Rule" failed to acknowledge its departure from past policy and practice, and ignored the "financial impact" of that departure. *Id.* at 92-94. The district court agreed with the hospitals and vacated the 2004 rule on both grounds. *Id.* at 89-93, 95.

The D.C. Circuit affirmed the vacatur, finding that "the Secretary's final rule was not a logical outgrowth of the proposed rule." *Allina I*, 746 F.3d at 1109. In so holding, it explained that "a party reviewing the Secretary's notice of proposed rulemaking understandably would have assumed that the Secretary was proposing to 'clarify' a then-existing policy, *i.e.*, one of excluding Part C days from the Medicare fraction and including them in the Medicaid fraction." *Id.* at 1108. The D.C. Circuit did not reach the reasonableness of the Secretary's decision-making in adopting the 2004 rule. *Id.* at 1111. The D.C. Circuit also did not reach the question of what procedures the agency would be required to follow in order to readopt the standard from the vacated rule. *Id.*

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[3] Like here, the Government there attempted to relitigate whether there had been any policy change. *See Allina I*, 904 F. Supp. 2d at 77 n.2 ("The Secretary's pretense in briefing the instant matter—that her current interpretation is entirely consistent with the past—is * ** clearly forestalled by *Northeast Hospital*. It is also irregular legal gamesmanship.").

D. The 2013 Prospective Rule

In mid-2013, while the Secretary's appeal in *Allina I* was pending before the D.C. Circuit, the agency engaged in a new prospective rulemaking on Part C days in the DSH payment as part of the annual inpatient prospective payment system rulemaking for 2014. 78 Fed. Reg. at 50,615. Effective October 1, 2013, the standard governing Part C days in the DSH calculation reverted to that articulated in the vacated 2004 rule. *See id.* at 50,619 (rule "readopt[ion]" applies to "FY 2014 and subsequent years" only).

E. This Case (*Allina II*)

1. In June 2014, sixteen days after the D.C. Circuit's mandate in *Allina I* vacating the 2004 rule, the Secretary issued 2012 Medicare fractions that included Part C days (consistent with the vacated 2004 rule) for hospitals nationwide. Pet. App. 5a-6a. Those fractions were published on the agency's website with an accompanying explanation that the fractions reflected the agency's decision to "includ[e] [Part C] Claims Submissions."[4] The agency proceeded without notice, comment opportunity, or explanation for the departure from the prevailing pre-2004 standard reinstated by the 2004 rule's vacatur.

Respondents filed appeals to the agency's Provider Reimbursement Review Board and requested expedited judicial review of their challenge to the renewed Part C days change. C.A. App. 89-167,

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[4] CMS, *DSH Adjustment and 2011-2012 File*, www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html.

178-248. The Board granted that request under 42 U.S.C. § 1395oo(f), concluding that it lacked authority "to decide the legal question of whether the regulation regarding the treatment of Medicare Part C days is valid and whether the Secretary's actions subsequent to the decision in *Allina* [*I*] are legal." Pet. App. 56a-58a, 71a-73a.

Respondents then brought this suit. The district court granted summary judgment to the agency. It found that the issuance treating Part C patients as Part A entitled was an "interpretative rule" exempt from the APA's notice-and-comment requirement, and that Medicare Act Section 1395hh(a)(2) incorporated the APA's exemption. Pet. App. 34a, 36a, 44a. The district court did not address Respondents' arguments about the independent notice-and-comment requirement of Section 1395hh(a)(4) triggered by the 2004 rule's "logical outgrowth" failure. Pet. App. 19a-44a.

2. The D.C. Circuit unanimously reversed. It explained that the text of Section 1395hh(a)(2) "describes in fairly straightforward language when notice and comment is necessary"—namely, "for any (1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services.'" Pet. App. 12a (citation omitted). The D.C. Circuit found all four elements "readily met." *Id.*

First, the D.C. Circuit reasoned that the agency's inclusion of Part C days as Part-A-entitled days in the 2012 Medicare fractions "is, at the very least, a 'requirement'" because those fractions, which must be

used for DSH payment determinations, "treat Part C enrollees as 'entitled to benefits under Part A.'" Pet. App. 12a-13a (citing 42 C.F.R. § 412.106(b)(2), (5)). Second, the 2012 issuance constituted a "change" because the agency's "baseline" before the invalidated 2004 rule "was to *exclude* Part C days from Medicare fractions." Pet. App. 13a (citing *Northeast Hosp.*, 657 F.3d at 15). Third, the D.C. Circuit found that the issuance promulgated a "substantive legal standard" because the fractions "define the scope of hospitals' legal rights to payment for treating low-income patients." Pet. App. 13a-14a. And fourth, because "[t]he fractions are used to calculate the payment that providers will receive for providing healthcare services to low-income patients," the inclusion of Part C days "governs 'payment for services.'" Pet. App. 14a. Consequently, "[t]he inclusion of Part C days means that the providers will now receive lower payments." *Id.*

The D.C. Circuit did not decide whether the "decision to include Part C days in the 2012 Medicare fractions was in fact an interpretive rule" because it rejected the Government's argument that the Medicare Act incorporates the APA's exception for interpretive rules. Pet. App. 15a, 17a. The D.C. Circuit "respectfully disagree[d]" with decisions from other circuits on that specific point based on the plain text of Section 1395hh(a)(2). *Id.* "Unlike the APA, the text of the Medicare Act does not exempt interpretive rules from notice-and-comment rulemaking." Pet. App. 15a. "On the contrary," the D.C. Circuit explained, "the text expressly *requires* notice-and-comment rulemaking. *** We must respect Congress's

use of different language and its establishment of different notice-and-comment requirements in the Medicare Act and the APA." Pet. App. 15a-16a.

The D.C. Circuit ruled, in the alternative, that "even if HHS were correct that the Medicare Act somehow incorporated the APA's notice-and-comment exception for interpretive rules, HHS would still not prevail" based on Section 1395hh(a)(4), another provision of the Medicare statute that "expressly required notice and comment in this case." Pet. App. 17a. The D.C. Circuit held that Section 1395hh(a)(4) precludes a provision from "becom[ing] legally operative until it has gone through notice-and-comment rulemaking" if that provision "is not a logical outgrowth of a previously published notice of proposed rulemaking.'" Pet. App. 17a-18a (citation omitted). The D.C. Circuit explained that "HHS could not circumvent this [Section 1395hh(a)(4)] requirement by claiming that it was acting by way of adjudication rather than rulemaking" because "[t]he statutory text says that the vacated rule may not 'take effect' at all until there has been notice and comment." Pet. App. 18a.

The Secretary's rehearing petition was denied, with no member of the court calling for a vote. Pet. App. 77a-78a, 79a-80a.

SUMMARY OF ARGUMENT

The D.C. Circuit held that two provisions of the Medicare Act, Section 1395hh(a)(2) and Section 1395hh(a)(4), independently require HHS to engage in notice-and-comment rulemaking before departing from the pre-2004 baseline for determining DSH

payments. That conclusion is correct and should be affirmed.

I. A. Section 1395hh(a)(2) requires notice and comment for (1) any "rule, requirement, or other statement of policy" (2) that "establishes or changes" (3) a "substantive legal standard" (4) governing "payment for services." 42 U.S.C. § 1395hh(a)(2). The Secretary's 2014 issuance falls squarely within that category of Medicare actions.

To start, the 2014 issuance "governs payments for services" because it directly affects DSH payments to hospitals for treating low-income patients—a point the Government here (despite its fluctuating views on the degree of payment impact) does not dispute.

The 2014 issuance is also the kind of agency action that can trigger the Medicare Act's notice-and-comment mandate. As the D.C. Circuit found, the 2014 issuance is at least a "requirement" (a term not used in the APA) as to DSH payments: The agency's Medicare fractions (and the standard they embody) are undisputedly binding on the agency's contractors in determining payments to hospitals, and even the agency's review Board concluded that it lacked authority to review their validity. In addition, the Government's own description shows that the 2014 issuance qualifies as a "statement of policy" guiding payment determinations. Its general application and future effect on payment rates also place it in the "rule" category. Neither the Government's ever-changing labels for its action nor its reliance on inapt precedent alters the commonsense conclusion that the

2014 issuance is the kind of agency instrument described in Section 1395hh(a)(2).

Next, the 2014 issuance made a "change." The vacatur of the 2004 rule restored the preexisting standard excluding Part C days from Part-A-entitled days in the Medicare fraction. From that baseline, the 2014 issuance plainly effected a change. The Government's retread position to the contrary—rejected in a 2011 D.C. Circuit decision on a full record and in subsequent decisions over years of litigation—cannot be squared with the relevant regulatory history.

Lastly, the 2014 issuance concerns a "substantive legal standard" because, as the D.C. Circuit found, the decision to include Part C days in the Medicare fraction "creates, defines, and regulates" the rights of hospitals. The statutory term "substantive legal standard" is not used in the APA and, regardless, should be understood according to its natural meaning as distinct from a "procedural" standard. The standard set by the 2014 issuance, filling a statutory gap to determine the treatment of Part C days, is anything but procedural.

B. The Government's principal argument—that Section 1395hh(a)(2) adopts the APA's "principles," and thus its "central distinction" between a "legislative" rule on the one hand and an "interpretive" rule lacking the "force and effect of law" on the other—is incompatible with the text, structure, and purpose of the Medicare Act. Far from incorporating the APA or its exemptions to notice and comment wholesale, Section 1395hh(a)(2) imposes a

different framework for notice-and-comment requirements specific to Medicare.

Under the Government's reading, only an agency issuance that already has "force of law" must go through the process typically used to give it that effect. But Section 1395hh(a)(2) explicitly *requires* notice and comment for a qualifying "statement of policy"—a type of issuance that ordinarily lacks the "force of law," and is categorically excluded from notice and comment under the APA. And making abundantly clear that Congress knew how to incorporate the APA's exceptions into the Medicare Act when it so intended, Section 1395hh(b)(2)(C) explicitly excuses the agency from notice-and-comment rulemaking under the Medicare Act when the APA's good-cause exception is satisfied. Congress's decision not to do the same for the APA's neighboring interpretive-rule exception speaks volumes.

The evolution of Section 1395hh's notice-and-comment requirement confirms what is readily apparent from the provision's text and structure. When it enacted Section 1395hh(a)(2), Congress took the unusual step of defining which policies HHS is required to promulgate through notice-and-comment regulation. Legislative history indicates that Congress was motivated to take that step based on a concern that "important policies [were] being developed without benefit of the public notice and comment period." H.R. REP. NO. 100-391(I), at 430. The Government's contrary characterization rests on out-of-context statements and speculative conclusions that ignore Congress's clearly articulated purpose.

II. Separate and apart from Section 1395hh(a)(2), Section 1395hh(a)(4) requires notice and comment in this case. That provision applies where, as here, a previous final rule has been invalidated for a "logical outgrowth" failure. In light of the 2004 rule's vacatur, the plain text of Section 1395hh(a)(4) precludes the inclusion of Part C days as Part A entitled from "taking effect" without notice and comment.

The Government's position—that HHS may avoid Congress's deliberate choice to require notice and comment following a logical-outgrowth failure by acting through instruments like the 2014 issuance that have the same nationwide effect—renders Section 1395hh(a)(4) a dead letter. Labeling it an "adjudication" cannot salvage the agency's end-run around Section 1395hh(a)(4) either, particularly in light of Section 1395hh(e)'s limitation on retroactive application of new policies—no matter how announced—to hospital services previously furnished.

III. Affirming the D.C. Circuit's decision will help, not hurt, the Medicare program. Congress required notice and comment for changes in substantive payment standards because hospitals must be able to plan and budget for health care services. They need an advance understanding of how much reimbursement they will receive from Medicare in order to fulfill their missions of serving the elderly and disabled beneficiaries in their communities. Accordingly, enforcing the Medicare Act's notice-and-comment requirements will facilitate planning of efficient and high-quality care for Medicare beneficiaries, which of course is the ultimate goal of the program.

The D.C. Circuit's holding will not impose the significant administrative burdens the Government suggests. In fact, its Section 1395hh(a)(4) holding has virtually no implications outside this case in light of the unique circumstances required to trigger that provision's notice-and-comment requirement. With respect to Section 1395hh(a)(2), the D.C. Circuit applied the plain terms of the statute to the unusual facts of this case—involving a change with billions of dollars at stake. Nothing about that holding will impose an undue burden on the agency, which already undertakes regular notice-and-comment rulemaking on a plethora of Medicare payment-related issues, including the DSH payment. Recent events, including a D.C. Circuit decision applying the decision below to find *no* notice-and-comment obligation under Section 1395hh(a)(2) for certain Medicare manual instructions, confirm that reality.

ARGUMENT

I. SECTION 1395hh(a)(2) REQUIRES NOTICE AND COMMENT HERE

When it enacted Section 1395hh(a)(2), Congress was concerned about the Secretary making sudden changes in Medicare payment standards without advance notice and input from the program's beneficiaries and service providers. For that reason, Congress created a notice-and-comment mandate unique to the Medicare program, instructing the agency to engage in notice-and-comment rulemaking whenever it issues a "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing *** payment

for services." 42 U.S.C. § 1395hh(a)(2). Unlike under the APA, the Medicare Act's notice-and-comment requirement applies if an agency issuance has the requisite standard-changing effect, regardless of the precise form of the issuance or the label the Government tries to affix. And it self-evidently applies to agency issuances—such as "statements of policy"—that are not "binding" on the agency or the courts and do not carry "the force and effect of law."

Because the 2014 issuance indisputably altered the legal consequences of treating low-income patients for hospitals across the country, it falls in the category of Medicare issuances subject to notice and comment. The Government's contrary arguments cannot be reconciled with the text, structure, or purpose of the Medicare Act.

A. The 2014 Issuance Fits Comfortably Within The Terms Of Section 1395hh(a)(2)

Section 1395hh(a)(2) requires notice and comment for the agency's renewed attempt at an about-face on Part C days in the DSH calculation. While the Government claims (contrary to its Petition) that the inclusion of Part C days as Part-A-entitled days would only "possibly reduce the amount of respondents' additional [DSH] payment" (Gov't Br. 4) (citation omitted), the Government (rightly) never disputes that the 2014 issuance "govern[s] *** payment for services." 42 U.S.C. § 1395hh(a)(2). And the issuance easily satisfies Section 1395hh(a)(2)'s other elements for triggering the notice-and-comment mandate.

1. "Rule, requirement, or other statement of policy"

a. As the D.C. Circuit found, the 2014 issuance "is, at the very least, a 'requirement.'" Pet. App. 12a. The Government admits that contractors (standing in for the agency's "own personnel") are *commanded* to use the Medicare fractions, which include Part C days as Part-A-entitled days, in calculating the amount of payment due to hospitals. Gov't Br. 5, 20. The contractors, acting on behalf of the agency, have no discretion on that issue. *See id.*

The Government asserts that the fractions are "based on" (Br. 11, 20, 37) and "reflect" (Br. 15, 17) a "nonbinding" interpretation of the DSH statute, and suggests a distinction between requirements on contractors and hospitals (Br. 40). But the Government does not and cannot dispute that hospitals are also *obligated* to use the published fractions (reflecting the agency's legal gap-filling) in their claims for DSH payments. 42 C.F.R. § 412.106(b)(2), (5).[5]

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[5] The Government also makes the puzzling claim that the term "requirement" does not mean what it says "in context." Gov't Br. 40. Rather than the Medicare Act, the Government invokes *American Hospital Association v. Bowen*, 834 F.2d 1037, 1051 (D.C. Cir. 1987). That APA case involved procedural enforcement-related "directives" to contractors engaging in "peer review" of Medicare outlays, which the court described as causing only "incidental inconveniences" for hospitals. *Id.* at 1041, 1051. It nowhere suggested that a requirement affecting both contractors *and* hospitals that *directly* results in substantially lower payments would be exempt from notice and comment

b. Tellingly, the Government makes no effort to explain why the 2014 issuance is not a "statement of policy." *See* Gov't Br. 39-41. The Government's contention that "not even respondents claim that their FY2012 fractions are 'statement[s] of policy'" (Br. 40) (alteration in original) is incorrect: Respondents made that argument below, and the Government (like here) offered no response. *See* Resp't C.A. Br. 25 ("[A]t the very least [the 2014 issuance] constituted a 'statement of policy.'"); Resp't C.A. Reply 11 ("The government does not dispute that *** the 2014 issuance is a *** 'statement of policy.'").

In fact, the Government's own description of the 2014 issuance demonstrates that it is (at a minimum) a "statement of policy." A statement of policy is typically "issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n.31 (1979) (quoting Attorney General's Manual on the Administrative Procedure Act 30 n.3 (1947)); *see, e.g., Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997) ("By issuing a policy statement, an agency simply lets the public know its current enforcement or adjudicatory approach.").

As the Government observes, when issuing "2012 Medicare fractions for hospitals nationwide," the agency explained that "the '[c]alculations *** includ[ed] [Part C] Claims Submissions.'" Gov't Br. 10

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under the APA (let alone under the yet-to-be passed Medicare Act provision imposing a separate notice-and-comment obligation for "requirement[s]").

(quoting *DSH Adjustment and 2011-2012 File*, p. 16, *supra*) (alterations in original). That explanation "reflected CMS's 'decision *** to include Part C days' in calculating the FY2012 Medicare fractions" based on its gap-filling "independent 'interpretation of the statute.'" Gov't Br. 11 (quoting Pet. App. 33a) (ellipses in original); *see Northeast Hosp.*, 657 F.3d at 13 (finding "statutory gap" in the DSH statute "for the Secretary *** to fill"). The Government further offers that the fractions "supply one aspect of the contractors' initial reimbursement determinations" and "are therefore just the first step in CMS's own administrative adjudicatory process." Gov't Br. 38. In that version of the Government's telling, then, the agency published a "statement of policy" to guide its adjudicatory approach to DSH payment determinations.

Notably, statements of policy are understood under the APA to be nonbinding. They "do[] not establish *** binding norm[s]" and are "not finally determinative of the issues or rights to which [they are] addressed." *American Hosp. Ass'n*, 834 F.2d at 1046 (citations omitted); *see also Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1014 (9th Cir. 1987) (citing multiple cases for proposition that statements of policy are not binding). For that reason, under the plain terms of Section 1395hh(a)(2), the Government's refrain that the challenged action could not trigger the Medicare Act's notice-and-comment requirement because it is "nonbinding" (*e.g.*, Gov't Br. 37-38) is misguided.

It is also wrong. As explained above, the issuance is binding on the agency's contractors and the

hospitals. The Government notes that contractor payment determinations are subject to review within the agency. Gov't Br. 38. But as the agency's Provider Reimbursement Review Board and the D.C. Circuit both held—and the Government no longer challenges—the Board had no authority to determine whether the 2014 issuance was valid and subject to the Medicare Act's notice-and-comment requirements. Pet. App. 10a-11a; *see id.* at 57a (Board explaining that it lacked authority "to decide the legal question of whether the regulation regarding the treatment of Medicare Part C days is valid and whether the Secretary's actions subsequent to the decision in *Allina* [*I*] are legal"). Given this limitation on the Board's authority, the 2014 issuance was binding on the agency's adjudicators as well.

c. The 2014 issuance also qualifies as a "rule." Section 1395hh(a)(2) does not define that term or distinguish between different categories of rules. The Government itself describes "[t]he challenged agency action [as], at most, an interpretive rule" (Br. 17), and contends that it "most resemble[s] *** the challenged provision" in *Shalala v. Guernsey Memorial Hospital* (Br. 39), which this Court held was an APA "interpretive rule," 514 U.S. 87, 99 (1995).[6] The district court accepted the Government's argument

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[6] *Guernsey* does not otherwise support the Government's construction of Section 1395hh(a)(2). That case involved a manual instruction that predated Section 1395hh(a)(2), and was decided under the APA. *See* 514 U.S. at 87.

below that the 2014 issuance was such an interpretive rule. Pet. App. 33a-34a.

That characterization comports with the APA definition of "rule." *See* 5 U.S.C. § 551(4).[7] When the agency resurrected its decision to treat Part C days as Part A entitled for purposes of the DSH payment adjustment to the base Medicare rates, it did so for all DSH hospitals across the country. Pet. App. 14a; *see* Gov't Br. 10 (confirming nationwide effect). The 2014 issuance was therefore one of "general applicability." Pet. App. 14a. And it had "future effect" because it was used to determine interim DSH payments to hospitals until the next year's fractions were issued in May 2015. *Id.* at 15a; *see* 75 Fed. Reg. 50,042, 50,282 (Aug. 16, 2010) (noting agency practice of "using each hospital's latest available [Medicare] fraction in determining [Medicare] interim payments from the time that the *** fractions are published until the *** fractions for the next fiscal year are published"); *see also, e.g., Mobil Oil Corp. v. Federal Power Comm'n*, 469 F.2d 130, 139 (D.C. Cir. 1972) ("These actions constitute rulemaking, despite their temporary nature.") (citations omitted).

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[7] The APA defines "rule," in pertinent part, as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy *** and includes the approval or prescription for the future of rates." 5. U.S.C. § 551(4).

2. "Change"

a. Prior to 2004, the agency's standard for determining patient days "entitled to benefits under Part A" in the DSH calculation excluded Part C days. At the time Part C was enacted, the then-existing DSH regulation counted as Medicare Part A entitled only patient days that were covered and paid under the Part A fee-for-service system. *See* pp. 10-11, *supra* (discussing pre-2004 regulatory scheme). Accordingly, as the D.C. Circuit has observed in decisions dating back to 2011, "between 1999 and 2004, the Secretary routinely *excluded* [Part C] days from the Medicare fraction." *Northeast Hosp.*, 657 F.3d at 15; *see also id.* at 17 (rejecting agency's argument that the exclusion of Part C days was inadvertent and finding that it reflected a conscious policy choice); *see* pp. 10, 13-15, *supra* (citing similar decisions).[8]

The vacatur of the 2004 rule, which had attempted a "volte-face," *Allina I*, 746 F.3d at 1109, restored the pre-2004 standard. *See, e.g., Croplife Am. v. EPA*, 329 F.3d 876, 879 (D.C. Cir. 2003) ("As a consequence [of vacating rule], the agency's previous practice *** is reinstated and remains in effect unless and until it is replaced by a lawfully promulgated

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[8] When the agency announced in 2004 that it would begin to "include the patient days for [Part C] beneficiaries in the Medicare fraction" (along with other days not covered and paid under Part A), the agency removed the word "covered" from the regulation governing the Medicare fraction. *See* p. 12, *supra* (describing change in regulatory text); *see also* 69 Fed. Reg. 48,916 (Aug. 11, 2004).

regulation."). Although the agency promulgated a new rule after notice and comment in 2013 that included Part C days as Part-A-entitled days, all agree that rule has only prospective effect and does not apply to the DSH fractions issued for years before 2014. As a result, "the pre-2004 standard of excluding Part C days from Medicare fractions remains the baseline" from which to evaluate the standard reflected in the 2012 DSH fractions at issue here. Pet. App. 13a. The agency's decision to *include* Part C days in those 2012 Medicare fractions was plainly a change from that baseline.

b. The Government does not directly challenge the D.C. Circuit's conclusion that the 2014 issuance constituted a "change" from the existing standard.[9] The Government instead contends that the D.C. Circuit's holding "cannot be right" because the agency would not have been permitted to apply *any* standard, including the pre-2004 standard. Gov't Br. 43. That is because the initial "establishment" of a standard either including or excluding Part C days, the Government says, would have triggered Section 1395hh(a)(2)'s notice-and-comment requirement. *Id.*

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[9] At the tail end of its separate Section 1395hh(a)(4) argument, the Government attempts to relitigate the D.C. Circuit's decision in *Northeast Hospital* by claiming that the 1990 rule governing HMO days—not the 1986 DSH regulation—"established" the pre-2004 standard governing Part C days. Gov't Br. 49. The D.C. Circuit soundly rejected that assertion based on a well-developed administrative record (*see* pp. 13-14, *supra*), and the Government offers this Court no new basis to disagree with that established finding (*see* pp. 54-55, *infra*).

As explained, however, the agency had no reason to engage in further notice-and-comment rulemaking before excluding Part C days from the Medicare fraction. It had already established the relevant standard, embodied in the 1986 regulation, through notice-and-comment rulemaking. *See* p. 11, *supra*. Indeed, the agency applied that standard until it finally implemented the 2004 rule in 2009 by way of Medicare fractions for 2007.

In any event, the agency had ample opportunity to engage in notice-and-comment rulemaking after the enactment of Part C to properly establish that standard. *See* 42 U.S.C. § 1395w-26(b)(1) (affording the agency nearly ten months to promulgate regulations for Part C plans); *see also* p. 7, *supra* (describing annual notice-and-comment rulemaking for inpatient hospital prospective payment system that includes the DSH payment).

The Government's (self-described) failure to do so then does not excuse its failure to do so now. In other words, the fact that the accepted pre-2004 policy and practice of excluding Part C days from Part-A-entitled days might *also* have required notice and comment in no way undermines the D.C. Circuit's conclusion that the challenged 2014 issuance changing that standard was procedurally invalid.

3. "Substantive legal standard"

The agency's 2014 issuance concerns a "substantive legal standard," a term unique to Section 1395hh(a)(2). As the D.C. Circuit explained, "'[s]ubstantive law' is law that 'creates, defines, and regulates the rights, duties, and powers of parties.'"

Pet. App. 13a-14a (quoting BLACK'S LAW DICTIONARY (10th ed. 2014)). It follows that a "substantive legal standard" includes a standard that "creates, defines, and regulates the rights, duties, and powers of parties." *Id.* The 2014 issuance sets this kind of substantive legal standard. Like the vacated 2004 rule attempting to adopt the same standard, the 2014 issuance "attaches new legal consequences to hospitals' treatment of low-income patients." *Northeast Hosp.*, 657 F.3d at 17.

The "principles" and definition the Government prefers over the Medicare Act's text relate to an APA "substantive rule," not a "substantive legal standard" as that term is used in Section 1395hh(a)(2) of the Medicare Act. Gov't Br. 25, 27.[10] But Congress in the Medicare Act did not just incorporate the APA in one fell swoop or reiterate the requirements of the APA. Instead, Congress used distinct terminology to mandate notice-and-comment rulemaking for any "rule, requirement or other statement of policy" setting a "substantive legal standard." That language is naturally read to exclude agency issuances governing *procedure*, while covering those altering *substantive* rights. *See Welch v. United States*, 136 S. Ct. 1257, 1264-1265 (2016) (contrasting "substantive" legal standards, which "alter the range of conduct or the class of persons that the law punishes," with "procedural" ones, which "regulate only the manner of determining the defendant's culpability") (citations

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[10] Even the APA recognizes that a "substantive rule" can encompass a rule that is "interpretive" in nature. *See* 5 U.S.C. § 553(d)(1), (2) (exempting "interpretive rules" from requirement applicable to "substantive rule").

and emphasis omitted). Even the Government seems to recognize that its contrary interpretation strays from common meaning. *See* Gov't Br. 27 ("[u]nderstanding th[e] specialized distinction" on which the Government's claim rests "requires specialized sources").

American Hospital Association—the D.C. Circuit case the Government touts as having "inspired" Section 1395hh(a)(2) (Br. 40)—supports the distinction between substance and procedure. Throughout its decision in that case, the D.C. Circuit emphasized the distinction not just between legislative and interpretive rules, but also between those two categories of rules (taken together) and a third category: "rules of agency *** procedure" (5 U.S.C. § 553(b)(A)) or "procedural rules." *See* 834 F.2d at 1044-1045, 1050-1052. If, as the Government contends, Section 1395hh(a)(2) reflects *American Hospital Association*, the D.C. Circuit's understanding of "substantive legal standard" must be correct. As that court has elsewhere recognized, the provision excludes issuances that alter agency procedures, including those that "set forth an enforcement policy." *Clarian Health West, LLC v. Hargan*, 878 F.3d 346, 355-356 (D.C. Cir. 2017); *see also Am. Hosp. Ass'n*, 834 F.2d at 1056-57 & n.4 (describing issuances setting forth agency enforcement priorities as "procedural rules"). But it covers those that "create[], define[], and regulate[] the rights, duties, and powers of parties"—whatever their form. Pet. App. 13a-14a.

The Government also contends that "the statute," not the 2014 issuance, "sets the governing standard" for purposes of Section 1395hh(a)(2). Gov't Br. 20.

But the Medicare statute's parameters governing the DSH payment adjustment leaves a "statutory gap" for the agency to fill (*i.e.*, which patients are "entitled to benefits under Part A"). *Northeast Hosp.*, 657 F.3d at 13. Because the 2014 issuance fills that gap, the issuance reflects a "legal" choice. *Id.*; *see also* Gov't Br. 11 (describing 2014 issuance as "based on the agency's independent interpretation of the statute") (citation omitted).

That choice is the relevant "standard" here. Consistent with that view, the Government has repeatedly used notice-and-comment rulemaking to implement new or revised standards on different categories of patient days in the DSH payment, including Part C days. *See* p. 10, *supra*. The Government's theory would exclude a large category of issuances with far-reaching impacts on Medicare providers from notice-and-comment rulemaking—exactly what Congress endeavored to avoid when it enacted Section 1395hh(a)(2).

B. The Government's Cramped Conception Of "Substantive Legal Standard" Contradicts The Medicare Act's Text And Purpose

Recognizing the constraints of the Medicare Act's text, the Government finds comfort in the "principles" of the APA. But Congress did not import the APA framework into the Medicare Act. Rather, it set out to require notice and comment for agency instruments that the agency might otherwise have tried to make effective without undertaking that process. Although the agency might prefer the APA, a Congress well

aware of the APA's contours did not enact the Medicare Act's special rulemaking provisions to be redundant.

1. Section 1395hh(a)(2) requires notice and comment for agency issuances that otherwise lack the "force of law"

a. The Government argues that Section 1395hh(a)(2) excludes from its notice-and-comment requirement any agency issuance that lacks "'the force and effect of law'" because such an issuance necessarily cannot "change" a "substantive legal standard." Gov't Br. 22. The Government's circular argument proves too much: The Medicare Act, by its terms, contemplates notice and comment for particular kinds of agency issuances—"rule[s], requirement[s], or other statement[s] of policy"—that would not otherwise have "the force and effect of law." The Medicare Act requires the agency to give these issuances that legal force before they can "take effect."

The words "force and effect of law"—which the Government borrows from inapposite APA decisions—are nowhere found in the Medicare Act. The Government's "force of law" argument relies on *Perez v. Mortgage Bankers Association*, 135 S. Ct. 1199, 1204 (2015). But in that case, this Court explained that the reason interpretive rules lack the force of law is that they have not gone through notice-and-comment rulemaking. *Id.* at 1204 ("The absence of a notice-and-comment obligation makes the process of issuing interpretive rules comparatively easier for agencies than issuing legislative rules. But[,] [as the Government recognizes,] that convenience comes at a

price: Interpretive rules do not have the force and effect of law.") (citation omitted); *see also* Gov't Br. 23 (explaining that a "legislative-type rule" has "binding legal force *because* it has been promulgated pursuant to" notice and comment) (emphasis added) (citing *Chrysler Corp.*, 441 U.S. at 302-303). Accordingly, the Government's contention—that interpretive rules are necessarily excluded from Section 1395hh(a)(2)'s notice-and-comment requirement because they lack the force of law—merely begs the question.[11]

b. Even more critically, the Government's "force of law" argument altogether ignores that "statement[s] of policy" in particular are expressly included in Section 1395hh(a)(2) as a type of instrument that can "establish[] or change[] a substantive legal standard." 42 U.S.C. § 1395hh(a)(2).

As noted above, statements of policy are not "binding" either on the agency or on the courts under the APA rubric. *See* pp. 28-29, *supra*. Nor do statements of policy carry "the force of law."[12] *See Am.*

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[11] The D.C. Circuit did not decide "whether HHS's decision to include Part C days in the 2012 Medicare fractions was in fact an interpretive rule," Pet. App. 15a, as opposed to a legislative-type rule. If this Court were to reverse the D.C. Circuit's interpretation of Sections 1395hh(a)(2) and (a)(4), it should remand for consideration of that unresolved question.

[12] The Government's attempt to equate "force of law" and "binding" (*see, e.g.*, Gov't Br 22) —neither of which appears in the Medicare Act—fails on both the facts (because the 2014 issuance is binding in every relevant respect, *see* pp. 26, *supra*) and the law. An APA interpretive rule is said to lack the "force of law" because it does not bind *courts*, even if it binds the agency

Hosp. Ass'n, 834 F.2d at 1046 (citations omitted). In fact, under the APA's framework, a statement of policy is markedly *less* capable of altering a legal norm than an interpretive rule. "Interpretive rules and policy statements are quite different agency instruments." *Syncor Int'l Corp.*, 127 F.3d at 94. With a policy statement, the "agency retains the discretion and the authority to change its position—even abruptly—in any specific case because a change in its policy does not affect the legal norm." *Id.*

By expressly including statements of policy among the types of issuances capable of triggering the notice-and-comment mandate, Congress made clear that Section 1395hh(a)(2) is not limited to agency issuances that carry "the force and effect of law." The Government's interpretation of "substantive legal standard" effectively reads "statements of policy" out of the statute (as well as "requirement[s]" that may also lack the force of law).

The Government also renders unnecessary Section 1395hh(a)(2)'s exclusion of "national coverage determinations" from its notice-and-comment requirement. *See* 42 U.S.C. § 1395hh(a)(2) (specifying any "rule, requirement, or other statement of policy

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(including its contractors and adjudicators). *See Chrysler Corp*, 441 U.S. at 308 (equating "binding effect of law" with being "binding on courts in a manner akin to statutes"); *see also* Gov't Br. 24 ("*courts* are *** not required" to give interpretive rules "binding effect of law") (emphasis added). It is passing strange to suppose that Congress's purpose to increase opportunities for public input (*see* pp. 44-45, *infra*) would be satisfied by a system where that opportunity comes by way of an after-the-fact lawsuit.

(*other than a national coverage determination*)") (emphasis added). Prior to Section 1395hh(a)(2)'s enactment, national coverage determinations were not issued through notice-and-comment rulemaking. *See* Omnibus Budget Reconciliation Act of 1986, § 9341 (providing that national coverage determinations were not to be "held unlawful or set aside" for failure to engage in notice and comment). If the Government were correct that Section 1395hh(a)(2)'s reference to a "substantive legal standard" limits the notice-and-comment requirement to legislative-type rules, there would have been no need for Congress to carve out national coverage determinations. As instruments "lacking the force and effect of law," they would have been excluded already.

c. Similarly, the Government gives short shrift to Section 1395hh(b)(2)(C), which demonstrates that Congress knew how to incorporate the APA's notice-and-comment exceptions into the Medicare Act when it intended to. Citing the section of the United States Code setting out the APA's rulemaking exceptions, the Medicare Act explicitly cross-references the good-cause exception. *See* 42 U.S.C. § 1395hh(b)(2)(C) (excusing notice and comment if "subsection (b) of section 553 of Title 5 does not apply pursuant to subparagraph (B) of such subsection"); *see also* 5 U.S.C. § 553(b)(B) ("good cause" exception).

In stark contrast, even though the APA's interpretive-rule exception is set out in the subparagraph immediately preceding the good-cause exception (Section 553(b)(A)), Congress did *not* cross-reference that exception—or any other APA exception

apart from good cause—in the Medicare Act. That deliberate omission leaves no doubt as to Congress's intent. *Cf. Russello v. United States*, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (alteration in original).

It is no answer to claim, as the Government does that "[t]here is *** no need for an express *exception* from that requirement for interpretive rules, because interpretive rules already are excluded from the scope of notice-and-comment rulemaking in the first place." Gov't Br. 28 (emphasis in original). Having explicitly cross-referenced one APA exception in Section 1395hh, it is inconceivable that Congress would hide another in a novel statutory phrase. Put simply, if Congress had intended to exclude interpretive rules from the scope of Section 1395hh(a)(2), it would have done so expressly.[13]

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[13] The Government's reference to the holdings of "other courts of appeals" that Section 1395hh(a)(2) "does not apply to interpretive rules" (Gov't Br. 28) is misleading. Those courts largely assumed, in footnotes without analysis (and not explicitly deciding), that the Medicare Act incorporated the APA's exceptions. *See, e.g., Warder v. Shalala*, 149 F.3d 73 (1st Cir. 1998); *Erringer v. Thompson*, 371 F.3d 625 (9th Cir. 2004). None adopted the new reasoning the Government offers this Court: that "substantive legal standard" should be read to exclude instruments that lack the force of law. Indeed, at the D.C. Circuit, the Government simply argued that the Medicare Act incorporated the APA's exception for interpretive rules *sub silentio*.

d. Several other surrounding provisions further undermine the Government's premise that an interpretive rule (or, a fortiori, a statement of policy) cannot change a "substantive legal standard" under Section 1395hh(a)(2). Section 1395hh(e)(1)(A) confers limited retroactive rulemaking authority for, inter alia, "substantive changes in *** interpretative rules, statements of policy, and guidelines of general applicability." That the Medicare Act contemplates "substantive changes" as part of an interpretive rule or statement of policy strongly supports the conclusion that those instruments can in fact change a "substantive legal standard" under the Medicare Act.

Section 1395hh(c)(1)(B) cuts the same way. That section imposes a separate obligation for the Secretary to "publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which *** are promulgated to carry out this subchapter, but *** are not published pursuant to subsection (a)(1)." In other words, it requires a published list of policy statements, rules, and instructions that do *not* trigger the notice-and-comment mandate of Section 1395hh(a)(2). That requirement presupposes that some such instruments must be issued via notice and comment.

The Government responds that Section 1395hh(c)(1)(B) does not shed light on Section 1395hh(a)(2) because the agency may engage in voluntary rulemaking. Gov't Br. 29. Anytime the agency issues interpretive rules through notice and comment, the Government contends, it does so voluntarily. *Id.* That unsupported contention not only

lacks any grounding in the statutory text, but it is contradicted by the legislative history of Section 1395hh(c)(1)(B). *See* H.R. REP. NO. 100-495, at 563 (1987) (Conf. Rep.) (Congress describing provision as necessitating publication of a list of "interpretative rules" "which *** are not published *as required* by [Section 1395hh(a)(2)]") (emphasis added).

2. Legislative history and context show Congressional intent to expand notice and comment

The evolution of the Medicare Act's notice-and-comment requirement reinforces the conclusion that Congress intended to expand the notice-and-comment obligations of the Secretary beyond what the APA requires.

Congress first added a notice-and-comment requirement to the Medicare Act in 1986, long after the agency had committed to following the APA. *See* 36 Fed. Reg. at 2,532 (stating in 1971 that the agency would "utilize the public participation procedures of the APA" in issuing "rules and regulations relating to *** benefits"). In that first enactment, Congress obligated the Secretary to provide 60 days for comment before publishing a Medicare regulation except in certain circumstances (such as when the APA's "good cause" exemption applies). *See* Omnibus Budget Reconciliation Act of 1986, § 9321(e). If there was a need to hold the agency to its notice-and-comment policy, *see* Gov't Br. 31, the 1986 enactment fully satisfied it.

But Congress did not stop there. Just one year later, in the face of widespread complaints about

standards governing payment still being issued without notice and comment, Congress revisited the specific Medicare rulemaking obligation. Noting its concern that "important policies [were] being developed without benefit of the public notice and comment period" because the Medicare Act did not "define a regulation for that [rulemaking] purpose," Congress took the unusual step of specifying "those policies which must be subject to the rulemaking procedures." H.R. REP. NO. 100-391(I), at 430.

In setting out the standard now codified in Section 1395hh(a)(2), Congress made clear that it intended to subject more policies to notice and comment than the agency had been promulgating through that process when it had been following the APA. In the initial House bill, the notice-and-comment requirement applied to any "rule, requirement, or other statement of policy" with a "significant effect on *** the payment for services." H.R. REP. NO. 100-495, at 563. The Conference Committee amended the provision's rulemaking trigger to the change or establishment of a "substantive legal standard" governing payment for services.

Congress never indicated that the change in wording was intended to have a limiting effect in the way the Government describes here. To the contrary, Congress stated its continued understanding that, pursuant to the conference amendment, any "[s]ignificant policy changes would be required to be promulgated as regulations." House Ways and Means Committee, Summary of Reconciliation Provisions, 12-13 (Dec. 22, 1987). Underscoring the breadth of the

notice-and-comment requirement, the heading enacted by the full Congress described the final provision as requiring "publication as regulations of significant policies," Omnibus Budget Reconciliation Act of 1987, § 4035 (capitalization omitted). The amendment therefore did not narrow the notice-and-comment requirement so as to exclude agency pronouncements like the 2014 issuance; if anything, it obviated any debate about the "significance" of such a pronouncement's "effect on payment."

The committee report's accompanying reference to "recent court rulings" (without citation) does not help the Government either. Even accepting the Government's speculation that the conferees were referring to the APA rulings that the Government chooses to cite, none of those discusses the phrase "substantive legal standard." And as discussed above, the case on which the Government primarily relies—the D.C. Circuit's decision in *American Hospital Association*—actually supports Respondents' reading that the phrase is intended to exclude only procedural (as opposed to substantive) pronouncements. *See* pp. 35-36, *supra*.

Finally, the Government claims that "nothing in the drafting history so much as hints that Congress had some other, novel administrative rulemaking procedures in mind when it enacted Section 1395hh(a)(2)." That is incorrect. The drafting history not only "hints" that Congress intended to create a separate notice-and-comment requirement under the Medicare Act, the history proves it. Congress did *not* import the APA's notice-and-comment requirement applicable only to certain rules, and it did *not* adopt

all of the APA's exceptions from that requirement when it dictated which agency issuances would be promulgated through notice and comment in 1987. To the contrary, it expressly included statements of policy (part of the APA's exception in 5 U.S.C. § 553(b)(A) and requirements (not mentioned in the APA) among the specific issuances subject to notice-and-comment rulemaking. Indeed, it is not clear what work the 1987 amendment does under the Government's theory. If the agency was statutorily obliged to follow the APA (with all its attendant exceptions) in 1986, and those same obligations and exceptions apply following the 1987 amendment, then the 1987 amendment accomplished nothing.

II. SECTION 1395hh(a)(4) INDEPENDENTLY REQUIRES NOTICE AND COMMENT HERE

Section 1395hh(a)(4) obligated HHS to undertake notice and comment before the change attempted by the vacated 2004 rule could again "take effect." That separate statutory provision, which applies *only* when a prior rule has been invalidated for a logical-outgrowth failure, is tailor-made for this case.

A. The Plain Terms Of Section 1395hh(a)(4) Require Notice And Comment In Light Of The 2004 Rule's Logical-Outgrowth Failure

Section 1395hh(a)(4) issues specific instructions to the agency: If a final regulation includes a provision that is not a "logical outgrowth" of the proposed regulation, then "*such* provision shall not take effect until there is the further opportunity for public

comment" and publication as a "final regulation." 42 U.S.C. § 1395hh(a)(4) (emphasis added).

When the agency—without providing a "further opportunity for public comment"—adopted in the 2014 issuance the same standard for Part-A-entitled days as in the vacated 2004 rule, it flouted Section 1395hh(a)(4)'s mandate. Section 1395hh(a)(4) does not permit a provision of a final rule invalidated for a "logical outgrowth" failure, such as the provision of the 2004 rule including Part C days as Part A entitled, to "take effect" through an instrument like the 2014 issuance. Without notice and comment, such a provision "shall not" become legally operative so as to alter the rights and obligations of regulated parties. *See* MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 397 (11th ed. 2012) (defining "effect" as "the quality or state of being operative"). But the 2014 issuance had precisely that (impermissible) result—mandating reduced DSH payments to hospitals for serving low-income patients.

As the Government recognizes (Br. 44), Section 1395hh(a)(4) is another departure from the APA. Under the APA, courts are directed to give "due account *** of the rule of prejudicial error," 5 U.S.C. § 706(2)(F), and have allowed procedurally invalid rules to stand without vacatur if the party challenging the rule cannot show that it was prejudiced by the error. *See, e.g., Allina I*, 746 F.3d at 1109-10 (discussing harmless-error rule and citing cases). Section 1395hh(a)(4) eliminates harmless-error analysis when a Medicare Act regulation has been invalidated for a logical-outgrowth failure: regardless

of prejudice, the offending provision will not "take effect."

B. The Applicability Of Section 1395hh(a)(4) Does Not Depend On How The Agency Tries To Make The Previously Invalidated Rule Take Effect

The Government contends that Section 1395hh(a)(4) has no application in this case because: (1) the 2014 issuance was not promulgated or required to be promulgated through a notice-and-comment regulation, and (2) the agency purportedly proceeded through adjudication without relying on the vacated 2004 rule. Neither allows the agency to dodge the requirements of Section 1395hh(a)(4).

1. The readoption of the 2004 rule need not take the form of a notice-and-comment regulation to trigger Section 1395hh(a)(4)

As the Government would have it, because Section 1395hh(a)(4) provides that an invalidated regulation cannot "take effect" without notice, comment, and republication as a "final regulation," only "final regulations"—*i.e.*, those that go through notice-and-comment rulemaking—trigger that provision. *See* Gov't Br. 44-45. That defies common sense.

For starters, the Government relies on the opening clause of Section 1395hh(a)(4) to argue that it applies only "[i]f the Secretary publishes a final regulation." Br. 18-19, 44 (alteration in original) (citation omitted). It then argues that because the

2014 issuance was not published as a final regulation, it falls outside the provision. *Id.* at 44-45. But Section 1395hh(a)(4)'s reference to "final regulation" in its opening clause clearly refers not to the agency action *after* the invalidation of a regulation, but to the original invalidated "final regulation that includes a provision that is not a logical outgrowth of" the proposed regulation, 42 U.S.C. 1395hh(a)(4)—here, the *2004 rule*.[14]

In reality, Section 1395hh(a)(4)'s later reference to "publication of the provision again as a final regulation" establishes the full contours of the Secretary's notice-and-comment obligation: a provision previously invalidated for a logical-outgrowth failure may become operative *only* as a final regulation issued through notice and comment. Accordingly, the question whether a particular issuance triggers Section 1395hh(a)(4) turns not on whether the agency has newly undertaken notice and comment as the Government claims, but on whether the agency tries to make the previously vacated provision of a prior invalidated rule "take effect."

The government's argument ignores the use of the same "take effect" language in Section 1395hh(a)(2), which bars any qualifying "rule, requirement, or other statement of policy" from

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[14]For the same reason, the Government's contention that "[i]t would make no sense to 'treat[]' [the 2014 issuance] *** 'as a proposed regulation'" (Br. 45 (quoting 42 U.S.C. § 1395hh(a)(4)) misses the mark. Section 1395hh(a)(4) does not require that the *2014 issuance* be treated as a proposed regulation; it requires such treatment for the vacated *2004 rule* in the context of new notice-and-comment rulemaking.

"tak[ing] effect" "unless it is promulgated by the Secretary *by regulation*." 42 U.S.C. § 1395hh(a)(2) (emphasis added). The explicit bar in Section 1395hh(a)(2) on qualifying issuances "tak[ing] effect" *absent* notice-and-comment rulemaking presumes that such issuance otherwise *could* very well otherwise "take effect" despite not being promulgated through notice-and-comment procedures. Because "take effect" means the same thing in Section 1395hh(a)(2) and (a)(4) (which even the Government agrees it must (Br. 44-45)), the "take effect" prohibition in Section 1395hh(a)(4) cannot apply only when an issuance readopting a provision of an invalidated final rule is later promulgated via notice-and-comment regulation.

As described above, the vacated 2004 rule "t[ook] effect" when the agency included Part C days as Part-A-entitled days in the Medicare fractions for all hospitals nationwide. When it actually published the renewed determination in 2014 to include Part C days as Part-A-entitled days, the agency offered no explanation for the standard's readoption, never mind any denial that it was applying the 2004 rule or the 2013 rule accomplishing the same. That the agency claims in a made-for-litigation affidavit that it did not "rel[y] on the vacated rule" itself in issuing the fractions (Gov't Br. 46) and instead applied the identical (invalidated) standard (as reflected in the agency's accompanying explanation) makes no difference.

As this case makes clear, the Government's interpretation of Section 1395hh(a)(4) creates an exception that would swallow it altogether. In the

Government's view, an agency issuance violates Section 1395hh(a)(4) *only if* the agency retains and implements a final regulation invalidated for logical-outgrowth failure. That result cannot be reconciled with Congress's deliberate decision in Section 1395hh(a)(4)—separate and apart from Section 1395hh(a)(2)—to require a new notice-and-comment period following a regulation's logical outgrowth-failure. And to the extent the Government makes the argument that Section 1395hh(a)(4) truly has no "independent force" (Br. 44-45) and rises and falls with Section 1395hh(a)(2), that argument defeats itself: Congress does not pass statutory provisions as window dressing. *See, e.g., TRW Inc. v. Andrews*, 534 U.S. 19, 31, (2001) ("[A] statute ought *** to be so construed that *** no clause, sentence, or word shall be superfluous, void, or insignificant.").

2. The agency's claim that it proceeded through adjudication does not avoid Section 1395hh(a)(4)

The agency's general authority to act through adjudication does not salvage the 2014 issuance. As an initial matter, the fractions do not "represent[] the agency's choice to proceed by adjudication rather than by rulemaking." Gov't Br. 46. The agency issued the fractions treating Part C days as Part A entitled for all DSH hospitals nationwide. That is not the "individual, *ad hoc* litigation" that typifies adjudication. *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947); *see* Pet. App. 18a (D.C. Circuit rejecting Government's claim it was proceeding through adjudication); Pet. App. 33a (district court rejecting same). Indeed, the Government otherwise calls the 2014 issuance "at

most" an interpretive rule, and describes it like a statement of policy. *See* pp. 27-30, *supra*. The fact that the fractions "supply one aspect" (Br. 38) of payment determinations does not convert the issuance into an adjudication. Under the government's theory, any substantive policy statement on Medicare payment rates could be an adjudication because all affect payment determinations.

But even if the 2014 issuance could qualify as an adjudication, it would still violate Section 1395hh(a)(4). Whether a provision previously invalidated for a logical-outgrowth failure "take[s] effect" through an "individual, *ad hoc* litigation," *Chenery Corp.*, 332 U.S. at 203, or (as here) through an issuance that applies simultaneously to hospitals across the country, the result is the same (here, the deprivation of significant payment for services to low-income patients). And it is precisely the result that Section 1395hh(a)(4) forbids.

Section 1395hh(e)(1), enacted at the same time as Section 1395hh(a)(4) (*see* pp. 6-7, *supra*), buttresses the conclusion that the form of the agency action does not matter under Section 1395hh(a)(4). Whether acting through rulemaking or adjudication, HHS may not apply "substantive changes" in regulations, interpretive rules, or statements of policy retroactively absent the requisite findings, and may not do so at all to enforce a new policy against a provider for services previously rendered. It is inconceivable that Congress intended to permit the agency in 2014 to act through "adjudication" and reinstate a policy covering 2012 services that was vacated for logical-outgrowth failure—*i.e.*, the *exact* circumstances governed by

Section 1395hh(a)(4)—when it could not make such a "substantive change" retroactively *even in the absence of a prior vacated rule* under Section 1395hh(e)(1).

The Government contends that the 2004 rule's vacatur left it "little choice but to address the handling of Part C patients by adjudication." Br. 48. Not so. Because the preexisting DSH regulation set forth a standard on Part-A-entitled days that excluded Part C days (pp. 11, 31, 33, *supra*), the agency could have (and should have) returned to the pre-2004 policy without any further action. The Government's (rehashed) claim that its pre-2004 standard in fact *included* Part C days in the Medicare fraction was rejected by the D.C. Circuit in an exhaustive 2011 opinion that examined agency policies dating back decades based on a full administrative record. *See Northeast Hosp. Ass'n*, 657 F.3d at 16; *see also* pp. 13-14, *supra*. The Government's attempt to relitigate that decision is too little, too late.

Regardless, the Government's claim that it had "little choice" but to act through adjudication falls flat no matter what standard came into effect following the 2004 rule's vacatur. Despite its statutory mandate to provide DSH payments, the agency has regularly delayed issuing DSH fractions—including in response to the *Allina I* litigation. *See* J.A. 24-26 (explaining that contractors were instructed to "immediately stop the issuance of Notices of Program Reimbursement (NPRs) for any cost reports that utilize a Social Security Income (SSI) ratio for determining DSH hospital payments, until further notice").

Moreover, the Medicare statute contemplates avoidance of notice-and-comment rulemaking when the agency can genuinely satisfy the good-cause exception, and permits retroactive rulemaking in certain limited circumstances. *See* 42 U.S.C. §§ 1395hh(b)(2)(C), (e)(1)(C). If the agency could not meet the statutory requirements for either good cause or retroactive rulemaking following the 2004 rule's vacatur, the answer was not to re-impose the same standard anyway. Whether framed as an adjudication or something else, that action violated Section 1395hh(a)(4).

III. AFFIRMING THE D.C. CIRCUIT'S DECISION WILL HELP, NOT HINDER, THE MEDICARE PROGRAM

The Government's brief (Br. 41-43) warns of the impact of the D.C. Circuit's decision on the agency's ability to administer the Medicare statute. But the singular focus on the agency's administrative burden ignores the many ways in which notice-and-comment rulemaking helps the Medicare system as a whole run more smoothly to the benefit of the elderly and disabled patients it serves. And the picture the Government paints about the supposed burden of rulemaking is divorced from the realities of the Medicare system and the tailored notice-and-comment requirements of Sections 1395hh(a)(2) and 1395hh(a)(4).

A. The Section 1395hh(a)(4) Holding Should Have Virtually No Implications Beyond This Case

As an initial matter, if the Court were simply to affirm the D.C. Circuit's Section 1395hh(a)(4) holding, the impact of its decision would be extremely limited. Section 1395hh(a)(4) applies in particular circumstances that are all but unique to this case. Leaving aside prior litigation over Part C days, no court has invalidated a Medicare rule for a logical-outgrowth failure, and only a handful of decisions have *ever* cited Section 1395hh(a)(4). *See* Br. in Opp'n 23-24 & n.4. Unless the Government intends to make a new habit of logical-outgrowth failures, Section 1395hh(a)(4) is unlikely to play any meaningful role in the administration of Medicare.

B. The Section 1395hh(a)(2) Holding Is Appropriately Narrow

The Government is also wrong to suggest that affirming the D.C. Circuit's Section 1395hh(a)(2) holding will have wide-ranging negative implications for the operation of Medicare.

First, to the extent that the holding changes the agency's Medicare practices at all, those changes will improve the program's ability to serve Medicare beneficiaries. Enacting more policies through notice and comment will increase predictability in the Medicare program and improve agency decision-making, including by prompting serious consideration of important factors such as financial impact. When providers are aware of the standards governing payment and can plan for reimbursements in advance,

they are better equipped to serve Medicare beneficiaries. Because the Medicare program makes $120 billion in expenditures each year just for inpatient hospital services and $675 billion in total, *see* https://www.cms.gov/fastfacts/, even seemingly small changes in payment standards yield significant changes in reimbursement for hospitals, *see County of Los Angeles v. Shalala*, 192 F.3d at 1010 ("Given the enormity of the Medicare program, *** seemingly modest percentage differences represent substantial sums of money.").

One need not look further than this case: As the Government admitted when it sought certiorari (after years of denials), whether Part C days are included in the Medicare fraction or the Medicaid fraction "makes a huge difference in the real world" (Pet. App. 4a) to hospitals. *See* Pet. 14 (asserting that the issue in this case affects $3 to $4 billion in Medicare payments). Indeed, avoiding the kind of "sticker shock" that occurred when the agency ultimately began treating Part C days as Part A entitled is precisely why Congress enacted Section 1395hh(a)(2). The Government now appears to backpedal on the financial impact it touted in order to obtain certiorari. *See* Gov't Br. 4-5. But the Government's apparent inability (or unwillingness) to acknowledge the financial impact of its change—even 14 years after first attempting to adopt it—only underscores the need for notice and comment.

In any event, affirming the D.C. Circuit is unlikely to change administrative practice to any great degree. Contrary to the Government's claim (Br. 42), the publication of binding fractions reflecting a

renewed change in national Medicare DSH payment policy has no bearing on the agency's ordinary use of instructions and manual guidance to its contractors. The publication of Medicare fractions is not a mere "instruction" to Medicare contractors. As described above (pp. 9, 26, *supra*), the fractions and the policy embodied in them are binding on all hospitals nationwide when they seek DSH payments in filing Medicare cost reports, and binding on the agency and its contractors in making payment determinations based on those cost reports. *See* 42 C.F.R. § 412.106(b)(2), (5) (requiring hospitals, the agency, and its contractors to use the agency's published Medicare fraction in calculating DSH payments).

By contrast, many contractor instructions neither (i) "establish[] or change[] a substantive legal standard," nor (ii) concern "the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits." 42 U.S.C. § 1395hh(a)(2). Section 1395hh(a)(2), by its terms, would not subject such mine-run procedural instructions to its notice-and-comment requirement.[15]

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[15] *See, e.g.*, Medicare General Information, Eligibility, and Entitlement Manual, CMS Pub. 100-01, ch. 6, §§ 10.1-10.4 (addressing release of information under Freedom of Information Act by CMS and its contractors), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c06.pdf; Medicare General Information, Eligibility, and Entitlement Manual, CMS Pub. 100-01, ch. 7, §§ 30-30.90 (describing record retention requirements for contractors), *available at* https://www.cms.gov/

Indeed, the D.C. Circuit has already had occasion to apply the decision below to certain Medicare manual instructions. It declined to require notice and comment, confirming the limited nature of its ruling in this case. *See Clarian Health West*, 878 F.3d at 356 (rejecting application of Section 1395hh(a)(2) to Medicare manual instructions governing enforcement as to reconciliation of special outlier payments). So it is utter hyperbole to suggest that the decision below "would, if taken to its logical conclusion, require CMS to promulgate all of its manuals and instructions, including the Provider Reimbursement Manual, through notice and comment." Gov't Br. 18.

Finally, contrary to the Government's suggestion, notice-and-comment rulemaking for Medicare payment standards, including for the DSH payment, is already the norm. Such rulemakings take a few months (not years, as the Government claims, Br. 42). As described above (p. 7, *supra*), the agency undertakes annual notice-and-comment rulemaking—taking an average of 102 days—for the inpatient hospital prospective payment system that includes the DSH payment. To the extent the D.C. Circuit's decision will result in fewer "guidance documents that effectively bind the public *without* undergoing the notice-and-comment rulemaking

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Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c07.pdf; Medicare Financial Management Manual, CMS Pub. 100-06, ch. 8, § 80.1 (describing contractor's qualifications for conducting a provider audit), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/fin106c08.pdf.

process," that would be consistent with current Executive Branch regulatory and enforcement policy. Memorandum from Associate Attorney General to Heads of Civil Litigating Components and United States Attorney, *re: Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases* (Jan. 25, 2018) (emphasis added); *see also Caring Hearts Personal Home Services, Inc. v. Burwell*, 824 F.3d 968, 976-77 (10th Cir. 2016) (Gorsuch, J.) (noting that "Madison worried about *** a world in which the laws are 'so voluminous they cannot be read' and constitutional norms of due process, fair notice, and even the separation of powers seem very much at stake").

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted.

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ADDENDUM

ADDENDUM

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5 U.S.C. § 551

Definitions

For the purpose of this subchapter—

* * * *

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing;

(5) "rule making" means agency process for formulating, amending, or repealing a rule;

(6) "order" means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

(7) "adjudication" means agency process for the formulation of an order;

* * * *

5 U.S.C. § 553

Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved--

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include--

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply--

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except--

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

42 U.S.C. § 1395w-21 (2012)

Eligibility, election, and enrollment

(a) Choice of medicare benefits through Medicare+Choice plans

(1) In general

Subject to the provisions of this section, each Medicare+Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits (other than qualified prescription drug benefits) under this subchapter--

(A) through the original medicare fee-for-service program under parts A and B of this subchapter, or

(B) through enrollment in a Medicare+Choice plan under this part,

and may elect qualified prescription drug coverage in accordance with section 1395w-101 of this title.

* * * *

(3) Medicare+Choice eligible individual

(A) In general

In this subchapter, subject to subparagraph (B), the term "Medicare+Choice eligible individual" means an individual who is entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter.

* * * *

42 U.S.C. § 1395hh (1982)

Regulations

The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

42 U.S.C. § 1395hh (Supp. IV 1986)

Regulations

(a) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(b)(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

42 U.S.C. § 1395hh (1988)

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where--

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of Title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which--

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

* * * *

42 U.S.C. § 1395hh.

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

* * * *

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed

rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where--

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of Title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules,

statements of policy, and guidelines of general applicability which--

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

* * * *

(e) Retroactivity of substantive changes; reliance upon written guidance

(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

* * * *

42 U.S.C. § 1395oo.

Provider Reimbursement Review Board

(a) Establishment

Any provider of services which has filed a required cost report within the time specified in regulations may obtain a hearing with respect to such cost report by a Provider Reimbursement Review Board (hereinafter referred to as the "Board") which shall be established by the Secretary in accordance with subsection (h) of

this section and (except as provided in subsection (g)(2) of this section) any hospital which receives payments in amounts computed under subsection (b) or (d) of section 1395ww of this title and which has submitted such reports within such time as the Secretary may require in order to make payment under such section may obtain a hearing with respect to such payment by the Board, if--

(1) such provider--

(A)(i) is dissatisfied with a final determination of the organization serving as its fiscal intermediary pursuant to section 1395h of this title as to the amount of total program reimbursement due the provider for the items and services furnished to individuals for which payment may be made under this subchapter for the period covered by such report, or

(ii) is dissatisfied with a final determination of the Secretary as to the amount of the payment under subsection (b) or (d) of section 1395ww of this title,

(B) has not received such final determination from such intermediary on a timely basis after filing such report, where such report complied with the rules and regulations of the Secretary relating to such report, or

(C) has not received such final determination on a timely basis after filing a supplementary cost report, where such cost report did not so comply and such supplementary cost report did so comply,

(2) the amount in controversy is $10,000 or more, and

(3) such provider files a request for a hearing within 180 days after notice of the intermediary's final determination under paragraph (1)(A)(i), or with respect to appeals under paragraph (1)(A)(ii), 180 days after notice of the Secretary's final determination, or with respect to appeals pursuant to paragraph (1)(B) or (C), within 180 days after notice of such determination would have been received if such determination had been made on a timely basis.

(b) Appeals by groups

The provisions of subsection (a) of this section shall apply to any group of providers of services if each provider of services in such group would, upon the filing of an appeal (but without regard to the $10,000 limitation), be entitled to such a hearing, but only if the matters in controversy involve a common question of fact or interpretation of law or regulations and the amount in controversy is, in the aggregate, $50,000 or more.

* * * *

(f) Finality of decision; judicial review; determinations of Board authority; jurisdiction; venue; interest on amount in controversy

(1) A decision of the Board shall be final unless the Secretary, on his own motion, and within 60 days after the provider of services is notified of the Board's

decision, reverses, affirms, or modifies the Board's decision. Providers shall have the right to obtain judicial review of any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or of any reversal, affirmance, or modification by the Secretary is received. Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider of services as described in the following sentence) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. If a provider of services may obtain a hearing under subsection (a) of this section and has filed a request for such a hearing, such provider may file a request for a determination by the Board of its authority to decide the question of law or regulations relevant to the matters in controversy (accompanied by such documents and materials as the Board shall require for purposes of rendering such determination). The Board shall render such determination in writing within thirty days after the Board receives the request and such accompanying documents and materials, and the determination shall be considered a final decision and not subject to review by the Secretary. If the Board fails to render such determination within such period, the provider may bring a civil action (within sixty days of the end of such period) with respect to

the matter in controversy contained in such request for a hearing. Such action shall be brought in the district court of the United States for the judicial district in which the provider is located (or, in an action brought jointly by several providers, the judicial district in which the greatest number of such providers are located) or in the District Court for the District of Columbia and shall be tried pursuant to the applicable provisions under chapter 7 of Title 5 notwithstanding any other provisions in section 405 of this title. Any appeal to the Board or action for judicial review by providers which are under common ownership or control or which have obtained a hearing under subsection (b) of this section must be brought by such providers as a group with respect to any matter involving an issue common to such providers.

* * * *

42 U.S.C. § 1395ww.

Payments to hospitals for inpatient hospital services

* * * *

(d) Inpatient hospital service payments on basis of prospective rates; Medicare Geographic Classification Review Board

* * * *

(5)(F)(i) Subject to subsection (r), for discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which--

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this subchapter or State plans approved under subchapter XIX), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

* * * *

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds--

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified

as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of--

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter and were entitled to supplementary security income benefits (excluding any State supplementation) under subchapter XVI of this chapter, and the denominator of which is the

number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, but who were not entitled to benefits under part A of this subchapter, and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under subchapter XI.

* * * *

(6) The Secretary shall provide for publication in the Federal Register, on or before the August 1 before each fiscal year (beginning with fiscal year 1984), of a description of the methodology and data used in computing the adjusted DRG prospective payment rates under this subsection, including any adjustments required under subsection (e)(1)(B).

42 C.F.R. § 412.106 (2003)

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation*: Federal fiscal year. For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of covered patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may

include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * *

42 C.F.R. § 412.106 (2004)

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation*: Federal fiscal year. For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may

include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * *

42 C.F.R. § 412.106 (2007)

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A (or Medicare Advantage (Part C)) and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that

period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage.* The

intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * *

42 C.F.R. § 412.106

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * *

(b) *Determination of a hospital's disproportionate patient percentage*—(1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A

(including Medicare Advantage (Part C)) and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A (including Medicare Advantage (Part C)).

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(iv) For cost reporting periods beginning on or after October 1, 2009, the hospital must report the days in the numerator of the fraction in the second computation in a cost reporting period based on the date of discharge, the date of admission, or the dates of service. If a hospital seeks to change its methodology for reporting days in the numerator of the fraction in the second computation, the hospital must notify CMS, through its fiscal intermediary or MAC, in writing at least 30 days before the beginning of the cost reporting period in which the change would apply. The written notification must specify the methodology

the hospital will use, the cost reporting period to which the requested change would apply, and the current methodology being used. Such a change will be effective only on the first day of a cost reporting period. If a hospital changes its methodology for reporting such days, CMS or the fiscal intermediary or MAC may adjust the number of days reported for a cost reporting period if it determines that any of those days have been counted in a prior cost reporting period.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * *

No. 17-1484

In the Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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In the Supreme Court of the United States

No. 17-1484

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR THE PETITIONER

I. SECTION 1395hh(a)(2) DID NOT REQUIRE NOTICE-AND-COMMENT HERE

A. The Medicare Act, *i.e.*, Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*, in Section 1395hh(a)(2), requires the Department of Health and Human Services (HHS) to promulgate "rule[s], requirement[s], or other statement[s] of policy" through notice-and-comment procedures *only* if they "establish[] or change[]" certain "substantive legal standard[s]." 42 U.S.C. 1395hh(a)(2). The Medicare Act also directs the agency to "provide * * * for an additional payment" each year to hospitals serving a disproportionate share of low-income patients, 42 U.S.C. 1395ww(d)(5)(F)(i), and instructs the agency how to calculate a certain quantity (the "Medicare fraction") used in one step of calculating the amount of that additional payment,

42 U.S.C. 1395ww(d)(5)(F)(vi)(I). That calculation requires the agency to include in the Medicare fraction patient days for patients who are "entitled to benefits under part A." *Ibid.* The underlying question in the parties' dispute is whether patient days for Part C patients, who by definition must be "entitled to benefits under part A," 42 U.S.C. 1395w-21(a)(3)(A), should be included in the Medicare fraction. The Centers for Medicare & Medicaid Services (CMS) instructed the contractors that make the initial determination of the reimbursement amounts hospitals will receive to include Part C patient days in calculating respondents' FY2012 Medicare fractions. But those calculations were not binding on the agency, on courts, or on respondents on subsequent review of the contractors' determinations. The calculation of those fractions thus did not change a substantive legal standard and so were not required by Section 1395hh(a)(2) to be promulgated as regulations using notice-and-comment procedures.

Respondents' brief only confirms that their contrary position has a fatal flaw: if (as respondents say) CMS's interpretation of the Medicare Act embedded in its instructions to its contractors "change[d]" a "substantive legal standard" and was thus required to be promulgated through notice-and-comment procedures, then respondents' alternative interpretation of the Medicare Act, which they say was applied previously by CMS, must have "establishe[d]" a "substantive legal standard" and was therefore likewise required to be promulgated through notice-and-comment procedures. 42 U.S.C. 1395hh(a)(2). And if that were true, the government would be prohibited from adopting respondents' preferred position, too—leaving the agency helpless to

adopt *any* interpretation of the statute without first going through notice-and-comment procedures, and thus unable to fulfill its statutory *duty* to "provide * * * for an additional payment" to respondents and other hospitals. 42 U.S.C. 1395ww(d)(5)(F)(i). That would be absurd. Seeking to avoid the absurdity, respondents claim that the agency had "no reason to engage in * * * notice-and-comment rulemaking" because the agency "had already established the relevant standard, embodied in the 1986 regulation." Resp. Br. 33.

Even the court of appeals did not rely on that reasoning, which is without merit. The 1986 regulation, 51 Fed. Reg. 16,772 (May 6, 1986), could not have addressed the question whether Part C patient days should be included in the Medicare fraction because Part C did not exist in 1986; it was enacted in 1997. Indeed the underlying question of statutory interpretation here is whether "entitled to benefits under part A" in Section 1395w-21(a)(3)(A) (defining the criteria to be a Part C patient) means the same as "entitled to benefits under part A" in Section 1395ww(d)(5)(F)(vi)(I) (defining the Medicare fraction). See Pet. Br. 4. The government maintains that the answer is yes; respondents say it is no. Either way, the interpretive question did not exist before 1997, because Section 1395w-21 did not exist before 1997. See Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4001, 111 Stat. 275-276 (enacting Section 1395w-21). So the 1986 regulation could not have definitively resolved that question.

Therefore, if respondents are correct that the agency's mere interpretation of the Medicare Act to calculate respondents' FY2012 Medicare fractions somehow "change[d]" a substantive legal standard, then *whichever* way the agency *first* interpreted Section

1395w-21 after its enactment in 1997 would have "establishe[d]" that substantive legal standard. 42 U.S.C. 1395hh(a)(2). And because the agency never promulgated the interpretation of the statute that respondents prefer through notice-and-comment procedures, the court of appeals would have erred in ordering the agency to adopt that reading of the statute. Respondents' position is thus not only incorrect but self-defeating. Under Section 1395hh and the longstanding principles of administrative law embodied in the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, that Section 1395hh(a)(2) was enacted to make applicable to the Medicare program, the agency may adopt interpretations of the Medicare Act without promulgating them through notice-and-comment rulemaking, and may later change its interpretation without undertaking notice-and-comment rulemaking. See *Perez* v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1207 (2015).

B. As the government's opening brief explains, the calculation of respondents' FY2012 Medicare fractions did not change a "substantive legal standard"—and thus did not need to be promulgated using the notice-and-comment procedures in Section 1395hh—for several reasons, including: (1) the calculation of the fractions is based on a nonbinding interpretation of the Medicare Act that is *at most* an interpretive rule to which the notice-and-comment procedures of Section 1395hh do not apply, Gov't Br. 22-37; (2) the fractions, which are simply one intermediate step in calculating respondents' ultimate reimbursement amounts for the year, do not bind the agency, the hospitals, or the courts, *id.* at 37-41; and (3) at all events the agency here

chose to proceed by adjudication rather than by rulemaking, *id.* at 46-49. Respondents' arguments to the contrary are unavailing.

1. a. The underlying statutory interpretation on which CMS's calculation of respondents' FY2012 Medicare fractions is based is *at most* an interpretive rule, for which subsection (a)(2) does not require notice-and-comment rulemaking. See Gov't Br. 21-29, 37-41. That is because interpretive rules do not carry the force and effect of law. Such rules thus by definition do not establish or change any "substantive legal standard," which is a necessary prerequisite for triggering the notice-and-comment requirement of subsection (a)(2). Respondents counter that subsection (a)(2) contains the term "statement[s] of policy"—a term that as used in the APA refers to statements of how an agency intends to exercise discretionary authority in the future and that also "are not 'binding' either on the agency or on the courts" and do not "carry 'the force of law.'" Resp. Br. 38 (citations omitted; brackets in original). Therefore, respondents conclude, "Congress made clear that Section 1395hh(a)(2) is not limited to agency issuances that carry 'the force and effect of law.'" *Id.* at 39.

But respondents' conclusion elides the critical phrase that follows in subsection (a)(2): "that establishes or changes a substantive legal standard." 42 U.S.C. 1395hh(a)(2). It is true enough that the opening words of subsection (a)(2) include "statement of policy," along with "rule" and "requirement," in identifying the forms a CMS action subject to the notice-and-comment requirement might take. *Ibid.* But subsection (a)(2) then uses limiting language—beginning with the restrictive modifier "that"—to confine the universe of "rule[s], requirement[s], or other statement[s] of policy" subject to

the notice-and-comment requirement to those "that establish[] or change[]" certain "substantive legal standard[s]." *Ibid.* Subsection (a)(2) thus makes clear that the *form* or *label* is immaterial: whether called a "rule," "requirement," or "statement of policy," a given issuance, however styled, must follow the specified notice-and-comment procedures only if it "establishes or changes a substantive legal standard." *Ibid.* That is why subsection (a)(2) does not require notice-and-comment procedures for interpretive rules; even though an interpretive rule may qualify as "rule," such a rule does not "establish[] or change[] a substantive legal standard" and thus falls outside the ambit of subsection (a)(2). *Ibid.*

Respondents' reliance (Resp. Br. 25, 27, 38-39) on the reference in Section 1395hh(a)(2) to a "statement of policy," in isolation, is misplaced in another respect as well. That provision's opening text makes it applicable to a "rule, requirement, or *other* statement of policy" that establishes or changes a substantive legal standard, 42 U.S.C. 13955hh(a)(2) (emphasis added), making clear that "statement of policy" as used in the subsection *includes* a "rule" and "requirement." Thus, subsection (a)(2)'s use of the term "statement of policy" cannot be understood to require notice-and-comment rulemaking for statements that merely explain how the agency intends to exercise its discretion in the future, especially when read together with the succeeding limitation to actions that establish or change a "substantive legal standard." *Ibid.*

b. For similar reasons, respondents' reliance on the express exclusion in subsection (a)(2) of national coverage determinations from the notice-and-comment requirement is misplaced. Resp. Br. 40. Respondents as-

sert that the exclusion is superfluous on the government's reading of subsection (a)(2) because "[a]s instruments 'lacking the force and effect of law,' [national coverage determinations] would have been excluded already." *Ibid.* To be sure, it has been the longstanding position of the government that national coverage determinations do not carry the force and effect of law and thus do not establish or change any substantive legal standard.[1] But that position was challenged in litigation, and at least one district court set aside a pre-1986 national coverage determination for failure to follow the APA's notice-and-comment procedures. See *Friedrich* v. *Secretary of Health & Human Servs.*, 894 F.2d 829, 832-833 (6th Cir.) (describing the district court's holding), cert. denied, 498 U.S. 817 (1990). Although the court of appeals reversed on the ground that the national coverage determination was an interpretive rule, not a legislative rule, *id.* at 837, the case demonstrates that the issue of whether national coverage determinations are legislative rules was a contested issue in the 1980s. It was hardly superfluous for Congress to make clear in 1986 that a national coverage determination "shall not be held unlawful or set aside" for failure to follow notice-and-comment procedures in either the APA or in Section 1395hh, as that had the salutary purpose and effect of eliminating all doubt. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a), 100 Stat. 2037-2038.[2]

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[1] Today, national coverage determinations are generally binding on contractors, administrative law judges, and the Medicare Appeals Council, see 42 C.F.R. 405.1060(a)(4), but not on the Departmental Appeals Board, see 42 U.S.C. 1395ff(f)(1)(A).

[2] As the Conference Report stated, the agency's process for promulgating national coverage determinations, codified today at

c. Respondents also erroneously rely (Pet. App. 13a-14a) on dictionary definitions that distinguish "substantive law" from "procedural law." See Resp. Br. 34-36. In the first place, even the definition respondents embrace supports the government's position, for it describes substantive law as "law that creates, defines, and regulates the rights, duties, and powers of parties." Pet. App. 13a-14a (quoting *Black's Law Dictionary* 1658 (10th ed. 2014)) (internal quotation marks omitted). That definition does not encompass interpretations of existing law, whether in the form of an interpretive rule or agency adjudication. See Gov't Br. 26.

In any event, as the government has explained, a definition based on a distinction between substance and procedure is the wrong definition to use in this context. See Gov't Br. 26-27. The appropriate definition is one distinguishing a substantive (or legislative) *rule* from an interpretive rule. See *id.* at 27-28. Contrary to respondents' suggestion, this is not a distinction that "strays from common meaning." Resp. Br. 35. "Substantive" has many meanings that are equally "common"; the key to understanding the applicable one is context. The context here—a statutory provision dealing with notice-and-comment procedures for an administrative agency—plainly calls for a meaning distinguishing substantive *rules* (which generally require notice-and-comment rulemaking under the APA) from interpretive rules (which do not). *Black's Law Dictionary*

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42 U.S.C. 1395y(*l*)(3), "is designed to assure consultation with the scientific and medical community and the general public," and so "the further procedure of publishing proposed and final regulations in the Federal Register does not seem essential." H.R. Conf. Rep. No. 1012, 99th Cong., 2d Sess. 350-351 (1986).

elsewhere draws that very distinction as well. See Gov't Br. 27-28.

d. Respondents similarly err in relying (Resp. Br. 42) on Section 1395hh(e)(1)(A), which allows retroactive application of a "substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability" under certain circumstances. 42 U.S.C. 1395hh(e)(1)(A). "That the Medicare Act contemplates 'substantive changes' as part of an interpretive rule or statement of policy," respondents say, "strongly supports the conclusion that those instruments can in fact change a 'substantive legal standard' under the Medicare Act." Resp. Br. 42. The conclusion does not follow from the premise, for respondents once again rely on an inapposite meaning of "substantive."

Here, the statute plainly intends to use the definition of "substance" meaning "the essential quality of something, as opposed to its mere form." *Black's Law Dictionary* 1656. After all, alongside "interpretive rules," subsection (e)(1)(A) also lists "manual instructions" and "guidelines of general applicability," 42 U.S.C. 1395hh(e)(1)(A), which do not establish or change a "substantive legal standard," 42 U.S.C. 1395hh(a)(2). This meaning of "substantive" is quite common—even used to describe changes to rules of *procedure*. Fed. R. Civ. P. 1 advisory committee's note (2007 Amendment) ("The style changes to the rules are intended to make no changes in substantive meaning."). Subsection (e)(1)(A) is thus of no assistance to respondents.

e. As the government has explained (Gov't Br. 30-37), the drafting history of Section 1395hh(a)(2) demonstrates that it was enacted to ensure that the Secretary would continue to follow the APA's notice-and-comment

requirements for substantive or legislative rules despite the APA's exception from that requirement for rules concerning "benefits," 5 U.S.C. 553(a)(2). That drafting history also confirms that by limiting the notice-and-comment requirement to actions that "establish[] or change[]" certain "substantive legal standard[s]," Congress expressly excluded the agency's nonbinding interpretations of the Medicare Act. Gov't Br. 30-37. Respondents note that the "initial House bill" required notice-and-comment rulemaking for actions that have a "significant effect on * * * the payment for services," and contend that the final enacted legislation means the same thing. Resp. Br. 44 (quoting H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. 563 (1987) (1987 Conf. Report)). But had Congress wanted to implement the House bill, it would have simply enacted it as it was worded; that the conference committee *changed* the language to "establishes or changes a substantive legal standard" strongly suggests that the enacted bill means something different from the House bill.[3]

Indeed, the government's opening brief explains (at 34, 36-37) that the committee changed the language to "reflect[] recent court rulings." 1987 Conf. Report 566. Such rulings could only have been in cases under the

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[3] Respondents also cite (Resp. Br. 44) a December 22, 1987 summary from the House Ways and Means Committee, but that generally worded summary did not address the specific question here, and it postdated both the conference committee's report and the final legislation's passage by the House and the Senate, making it of questionable interpretive value in any event. Indeed the summary expressly says it "should not be construed as an official record reflecting the conference agreement." H.R. Comm. on Ways and Means, 100th Cong., 1st Sess., *Summary of Conference Agreement on Reconciliation Provisions Within the Jurisdiction of the Committee on Ways and Means*, at III.

APA, and they included the then-recent ruling in *American Hospital Association* v. *Bowen*, 834 F.2d 1037 (D.C. Cir. 1987). *American Hospital Association* reiterated that the APA's notice-and-comment requirement applies only to "*substantive* rules" that "create *law*" and "establish[] a *standard* of conduct which has the force of law," *id.* at 1045-1046 (emphases added; citations omitted)—language plainly echoed in the text of Section 1395hh(a)(2) that the conference committee adopted and Congress enacted. True, as respondents point out (Resp. Br. 35), *American Hospital Association* also stated that *procedural* rules need not be promulgated through notice-and-comment rulemaking either. 834 F.2d at 1050-1051. But that statement does not mean that all non-procedural rules must go through notice and comment. Rather, the court was merely emphasizing that a rule must be *both* non-interpretive *and* non-procedural to trigger the APA's notice-and-comment requirement. *Id.* at 1046, 1051.

The key point is that Congress enacted Section 1395hh for one specific purpose: to require HHS to comply with *the APA* in promulgating certain regulations regarding payment for services. See Gov't Br. 35-37. Congress did that by incorporating APA standards into the Medicare Act. See *ibid.* Nothing in the drafting history of the 1986 or 1987 amendments to Section 1395hh suggests that Congress intended to import anything other than ordinary and longstanding administrative law principles into the Medicare Act. Under those principles, an agency's nonbinding interpretation of the statute it administers (*i.e.*, an interpretive rule) does not, by definition, establish or change any substantive legal standard. Respondents neither contest this simple point nor explain why, if Congress had wanted to

deviate significantly from these principles, it would have done so by incorporating language from "recent court rulings" *interpreting the APA* into Section 1395hh and rejecting the broader language in the House proposal. 1987 Conf. Report 566.

2. a. Respondents do not meaningfully defend the court of appeals' reasoning that the FY2012 Medicare fractions calculated and posted on CMS's website are "binding" in a sense that would require notice-and-comment rulemaking simply because the agency's own private contractors must adhere to them in making payment determinations. Cf. Pet. App. 12a-13a. Rather, respondents repeatedly insist that the FY2012 Medicare fractions are binding on hospitals. *E.g.*, Resp. Br. 9, 26, 28-30, 38 & n.12, 57. Specifically, respondents claim that "the fractions and the policy embedded in them are binding on all hospitals nationwide * * * in filing Medicare cost reports." *Id.* at 57. But hospitals remain free to challenge not only the calculated fractions, but also the ultimate reimbursement determinations that are made using those fractions, in administrative proceedings and, eventually, in court. See 42 C.F.R. 405.1835(b)(2)(ii). Indeed that is precisely what respondents did here.

The authority respondents cite (Resp. Br. 9, 57) for their contrary position, 42 C.F.R. 412.106(b)(2) and (5), simply begs the question—for that is the regulation defining the Medicare fraction in the first instance. See generally Gov't Br. App. 19a-27a (reproducing the 2003, 2004, and current versions of the regulation). The version applicable to this dispute says simply that the Medicare fraction includes in the numerator patient days for patients "entitled to both Medicare Part A and SSI," 42 C.F.R. 412.106(b)(2)(i)(B) (2003) (reproduced at

Gov't Br. App. 20a), which does not answer the question whether Part C patients days count.[4] As a result, absent a final judgment in an adjudication, the agency's inclusion of Part C patient days in respondents' FY2012 Medicare fractions is itself not binding on anyone but the agency's own contractors.

Therefore, neither the FY2012 fractions nor the statutory interpretation on which they are based is binding in the relevant sense—not on hospitals, not on the agency, and not on courts. As with all instructions to its own contractors—such as the Provider Reimbursement Manual provision the Court held was an interpretive rule in *Shalala* v. *Guernsey Memorial Hospital*, 514 U.S. 87, 97, 99-100 (1997)—the agency's computation of respondents' FY2012 Medicare fractions "bind neither CMS nor the Board in adjudications," "do not change the legal standards that govern the hospitals," and "do not change the legal standards that govern the agency." *Clarian Health West, LLC* v. *Hargan*, 878 F.3d 346, 355-356 (D.C. Cir. 2017).

b. Respondents briefly assert (Resp. Br. 29) that CMS's publication of their FY2012 Medicare fractions must have been binding on the agency because respondents successfully obtained expedited judicial review, which is available if "the Board determines * * * that it is without authority to decide" a "question of law or regulations." 42 U.S.C. 1395*oo*(f)(1); see 42 C.F.R. 405.1842. Respondents misapprehend the reason *why* they were able to obtain expedited judicial review. It was not because the Provider Reimbursement Review Board thought itself bound by the FY2012 fractions.

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[4] The current version makes clear that "entitled to * * * Medicare Part A" "includ[es] Medicare Advantage (Part C)" patient days. 42 C.F.R. 412.106(b)(2)(i)(B) (reproduced at Gov't Br. App. 25a).

See Pet. App. 71a-73a. Rather, the Board allowed expedited judicial review because respondents *framed* their case as a "challenge" to the "procedural validity of" a purported "regulation" issued by CMS following the remand in the previous *Allina* case. 42 C.F.R. 405.1842(f)(1)(ii); see Pet. App. 70a-71a. The court of appeals agreed, but held that the Board's decision was not reviewable. Pet. App. 10a-11a. But of course the very dispute here is whether respondents' FY2012 Medicare fractions, or the underlying statutory interpretation on which the fractions were based, must be promulgated as a "regulation" under Section 1395hh in the first place. 42 U.S.C. 1395hh(a)(2). To bootstrap respondents' own framing of their challenge into a legal conclusion about the binding nature *vel non* of CMS's instructions to its own contractors would be entirely circular.

3. At all events, the government's opening brief explains (at 46-49) that Section 1395hh does not apply at all when the agency chooses to proceed via case-by-case adjudication rather than by rulemaking. Respondents assert that this case involves the agency's attempt to fill a "statutory gap," and thus *must* be accomplished by promulgating a regulation. Resp. Br. 36 (citation omitted). As discussed earlier, this assertion only underscores the incorrectness of respondents' argument: if there is indeed a statutory gap, and if (as respondents maintain) it can be filled only through notice-and-comment rulemaking, then the agency would have had to undertake notice-and-comment rulemaking even to adopt *respondents'* preferred interpretation of the statute, for that would fill the purported gap no less than the government's interpretation of the statute.

Regardless, an agency always remains free to choose whether to fill a statutory or interpretive gap by rulemaking or by adjudication. *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). Nothing in the text of Section 1395hh(a)(2) displaces that fundamental principle of administrative law; to the contrary, subsection (a)(2) applies only to "rule[s]", "regulation[s]" and "other statement[s] of policy"—not to adjudications.

Here, after the D.C. Circuit vacated the 2004 regulation in a 2014 decision, see Gov't Br. 9, 47-48, the agency had little choice but to fill the alleged "gap" for fiscal years between 2004 and 2014 through case-by-case adjudication. In doing so, the agency interpreted the statutory text and concluded that "entitled to benefits under part A" in 42 U.S.C. 1395w-21(a)(3) has the same meaning as "entitled to benefits under part A" in 42 U.S.C. 1395ww(d)(5)(F)(i)(I) does. That the agency's attempt to adopt this legal position by regulation failed did not in any way deprive it of the power to adopt this legal position by adjudication. *Bell Aerospace*, 416 U.S. at 292.

Respondents also argue that it begs the question to say that an agency action lacking "the force and effect of law" need not be promulgated through notice-and-comment procedures because it is the notice-and-comment procedures themselves that give the action such force and effect. Resp. Br. 37-38 (citation omitted). But an agency can *choose* to promulgate through notice-and-comment rulemaking a statutory interpretation that it could otherwise issue in another form, such as by inclusion in the Provider Reimbursement Manual, that does not require notice and comment. Moreover, if respondents' contention were true, it would also be true of the APA, which exempts from its notice-and-comment

requirements interpretive rules and statements of policy, which by definition do not have the force and effect of law. See 5 U.S.C. 553(b)(3)(A); *Mortgage Bankers Assn.*, 135 S. Ct. at 1208. Regardless, as described above, agencies are entitled to adopt a legal position through case-by-case adjudication rather than by regulation, *Bell Aerospace*, 416 U.S. at 294, and, as under the APA, a final adjudicative decision by the Secretary (which we do not have here because respondents short-circuited the administrative review process) would bind the parties—all of whom would have had the chance to be heard. See 42 C.F.R. 405.1875(e)(4). Section 1395hh(a)(2) does not displace this fundamental principle of administrative law either.

II. SECTION 1395hh(a)(4) DID NOT INDEPENDENTLY REQUIRE NOTICE-AND-COMMENT RULEMAKING HERE

If subsection (a)(2) did not require the agency to engage in notice-and-comment rulemaking here, subsection (a)(4) does not provide an independent basis to conclude otherwise. See Gov't Br. 44-46. That is because subsection (a)(4) applies only to a "regulation" promulgated through notice-and-comment procedures in the first instance. See *ibid.* Therefore, if CMS's publication of respondents' FY2012 fractions changed a relevant substantive legal standard, then subsection (a)(2) is sufficient for respondents to prevail; it is unnecessary to rely on subsection (a)(4). If, on the other hand, CMS's publication of the FY2012 fractions did *not* change a relevant substantive legal standard, then that action was not subject to the Medicare Act's notice-and-comment requirements at all—not the one in subsection (a)(2), and not the one in subsection (a)(4). Contrary to re-

spondents' assertion (Resp. Br. 51), that does not render subsection (a)(4) "window dressing." Rather, subsection (a)(4) simply provides an *additional* requirement for regulations promulgated through notice-and-comment procedures. Here, however, the challenged agency action is not the promulgation or enforcement of a "regulation" in the first instance.

Respondents also assert that subsection (a)(4) applies because the government is attempting to give "effect" to the vacated 2004 regulation. Resp. Br. 49-50. Not so. CMS, in publishing respondents' FY2012 fractions, did not give effect to the regulation; it gave effect to the Medicare Act as it understood the Act—specifically, the statutory provision defining the Medicare fraction, 42 U.S.C. 1395ww(d)(5)(F)(vi)(I). As the district court unequivocally found, "[respondents'] posted 2012 SSI fractions were not calculated in reliance on the vacated rule." Pet. App. 105a. Instead, the agency "appropriately relied on and interpreted the underlying [Medicare] statute to calculate" the FY2012 fractions. *Id.* at 31a.

Finally, respondents assert that even when an agency chooses to proceed through adjudication, it cannot achieve the same "result" as giving effect to a regulation that would violate the logical-outgrowth requirement of subsection (a)(4). Resp. Br. 52. That is incorrect, and respondents do not cite any authority to support that assertion. Rulemaking and adjudication are *alternative* means for an agency to carry out its functions. *Bell Aerospace*, 416 U.S. at 294; *SEC* v. *Chenery Corp.*, 332 U.S. 194, 201 (1947). Rulemaking has certain advantages, see Gov't Br. 47, but a rulemaking that is ineffective on procedural grounds does not forever tarnish the legal position set forth in the pro-

posed rule. The agency remains free to adopt the position through case-by-case adjudication. That is what the agency did in the earlier *Allina* litigation after the 2004 rule had been vacated. See Gov't Br. 9; *Allina Health Servs.* v. *Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014); see also *Allina Health Servs.* v. *Burwell*, No. 16-cv-150 (D.D.C. filed Jan. 29, 2016) (challenging the decision of the CMS Administrator on remand). Indeed, this Court made clear in *Bell Aerospace* that an agency could employ case-by-case adjudication to set forth its position *even if* that position "previously had been spelled out in a general rule or regulation." 416 U.S. at 292 (citation omitted). Respondents do not even cite, much less address, *Bell Aerospace* and the bedrock rule of administrative law that it reiterates.

III. RESPONDENTS' POSITION WOULD SUBSTANTIALLY UNDERMINE THE AGENCY'S ABILITY TO ADMINISTER THE MEDICARE PROGRAM

As the government has explained, respondents' theory, if adopted, has the potential to substantially undermine effective administration of the Medicare program, not least because its rationale would encompass not just the Medicare fractions at issue here but nearly every instruction to the agency's contractors, including those contained in the Provider Reimbursement Manual. Gov't Br. 41-43. That would run afoul of this Court's holding in *Guernsey*, which held that interpretive rules predating the 1986 amendments to Section 1395hh, including the Provider Reimbursement Manual provision at issue in that case, need not go through the APA's notice-and-comment procedures. 514 U.S. at 98-99.

Respondents do not meaningfully respond to this concern, distinguishing *Guernsey* solely on the basis that it was "decided under the APA," Resp. Br. 29 n.6,

without explaining either how their theory here would not undermine *Guernsey* or why Section 1395hh(a)(2) should be construed to do so, given that Congress chose to incorporate APA rulemaking principles into the Medicare Act. Indeed *Guernsey* recognized that issuing interpretive rules and guidance to contractors that do not bind the agency or courts can be "a sensible structure for the complex Medicare reimbursement process." 514 U.S. at 101. Respondents' reassurance that not *all* contractor instructions "concern 'the payment for services, or the eligibility or individuals, entities, or organizations to furnish or receive services or benefits,'" Resp. Br. 57 & n.15 (citation omitted), rings hollow, for a significant number of contractor instructions (including much of the Provider Reimbursement Manual) *do* concern those areas. Respondents' theory, if accepted, would appear to subject all of those to notice-and-comment rulemaking requirements. That would substantially undermine the agency's ability to administer the broad and complex Medicare program, in contravention of the plain text of Section 1395hh limiting the notice-and-comment requirement to issuances that establish or change a "substantive legal standard." Nothing in Section 1395hh suggests that Congress intended to impose such drastic constraints on CMS.

* * * * *

For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted.

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JANUARY 2019

No. 17-1484

IN THE

Supreme Court of the United States

ALEX M. AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

ALLINA HEALTH SERVICES, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF THE AMERICAN HOSPITAL ASSOCIATION, FEDERATION OF AMERICAN HOSPITALS, AND ASSOCIATION OF AMERICAN MEDICAL COLLEGES AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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IN THE

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ALEX M. AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES,

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BRIEF OF THE AMERICAN HOSPITAL ASSOCIATION, FEDERATION OF AMERICAN HOSPITALS, AND ASSOCIATION OF AMERICAN MEDICAL COLLEGES AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

STATEMENT OF INTEREST

The American Hospital Association, Federation of American Hospitals, and Association of American Medical Colleges respectfully submit this brief as *amici curiae*.[1]

[1] No party or counsel for a party authored or paid for this brief in whole or in part, or made a monetary contribution to fund the brief's preparation or submission. No one other than *amici* or their members or counsel made a monetary contribution to the brief. All parties have consented to the filing of this brief.

The American Hospital Association (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations. AHA members are committed to improving the health of the communities they serve and to helping ensure that care is available to and affordable for all Americans. The AHA educates its members on healthcare issues and advocates to ensure that their perspectives are considered in formulating health policy.

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. FAH's members include teaching and non-teaching hospitals in urban and rural America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. Dedicated to a market-based philosophy, the Federation provides representation and advocacy on behalf of its members to Congress, the Executive Branch, the judiciary, media, academia, accrediting organizations, and the public.

The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 152 accredited U.S. and 17 accredited Canadian medical schools, nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The question presented here is of tremendous importance to *amici*'s members. The federal Medicare

program enables *amici*'s members to provide the wide range of critical healthcare services on which their patients and communities rely. And the patients and communities for whom this issue of Medicare administration matters most are among the country's most vulnerable.

By evading the notice-and-comment process required by 42 U.S.C. § 1395hh(a)(2), the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) were allowed to impose their own substantive policy views without understanding their direct impact on healthcare providers and those they serve. That procedural shortcut leads to policies that harm those affected by them, as well as inconsistency and uncertainty in how providers' Medicare reimbursements may be determined from year to year. Because "[n]otice and opportunity for comment are critically important for determining and meaningfully considering the true impact of any payment policy change on hospitals" (Br. in Opp. 38), the Court should affirm the judgment below.

SUMMARY OF ARGUMENT

I. Notice and comment is a mainstay of administrative law. Rightly so. Notice and comment is a critical procedural protection that enables public participation for those stakeholders most likely to be affected by contemplated agency policymaking and allows agencies' decisionmaking to be informed and responsive. To be sure, adding this additional layer of protection comes with certain trade-offs. But when an agency seeks to create, define, and regulate the rights, duties, and obligations of parties in a manner that entails substantial real-world impact,

notice and comment should be required. And for changes that alter the substantive legal standards governing Medicare payments, Congress has mandated precisely that. *See* 42 U.S.C. § 1395hh(a)(2).

The size and scope of the federal Medicare program demonstrate why notice and comment is essential for agency conduct altering payment policies. Even seemingly minor changes carry the potential for enormous consequences. The extensive history of this litigation, including CMS's repeated attempts to evade the specific payments due Respondents, reflects the stakes for agency action, even if the agency tries to underplay the significance of those actions. Had the proper procedures been followed from the outset, the parties and the public alike would have benefitted from the notice and comment Congress prescribed for exactly these circumstances.

II. Congress here required the opportunity for public participation through notice and comment before HHS and CMS could alter the Disproportionate Share Hospital (DSH) fraction calculations that determine the payments due providers under the DSH program. The text of Section 1395hh(a)(2), distinct from the Administrative Procedure Act (APA), extends to *any* change to the substantive legal standards governing Medicare payments. Petitioner's after-the-fact justification offered in defense of CMS's decision to forgo notice and comment by labeling its Medicare-fraction calculations "interpretive only" lacks merit.

That Congress required CMS to undertake notice and comment here does not mean CMS must *always* do so. Nor does the fact-sensitive decision below render the Medicare program unworkable more

broadly. True guidance documents, which instruct but do not dictate, need not go through notice and comment, as subsequent case law applying the decision below confirms. *See Clarian Health W., LLC* v. *Hargan*, 878 F.3d 346 (D.C. Cir. 2017). The decision below therefore will not upset HHS and CMS's administration of the Medicare program.

The Court should affirm the D.C. Circuit's judgment.

ARGUMENT

I. NOTICE AND COMMENT FOR SUBSTANTIVE LEGAL STANDARDS IMPLEMENTING THE MEDICARE ACT IS ESSENTIAL GIVEN MEDICARE'S SIZE AND SCOPE.

Congress required notice and comment for any "rule, requirement, or other statement of policy" that "changes a substantive legal standard governing" payments for Medicare services, 42 U.S.C. § 1395hh(a)(2), for good reason. When it comes to Medicare, seemingly small changes can have outsized results. This case is a perfect example. Whether Part C days count in the Medicare or Medicaid fraction has substantial real-world impact. That decision alone affects billions of dollars of federal funding according to the Government's own estimate. *See* Pet. 14. It is precisely the sort of substantive legal standard that should be subject to public input.

1. Medicare is a program of great importance to the health of our nation. Total Medicare benefits entailed more than $700 billion in federal spending in 2017, almost double the $425 billion spent in 2007. Juliette Cubaski & Tricia Neuman, *The Facts on Medicare Spending and Financing*, Henry J. Kaiser

Family Foundation (June 22, 2018).[2] Medicare expenditures were also 15 percent of total federal spending in 2017; by 2028, Medicare's share is expected to rise to 18 percent. *See id.* And Medicare alone accounts for roughly 20 percent of the $3.3 trillion a year spent on health care nationally. *See* Centers for Medicare & Medicare Servs., *National Health Expenditure Data: Historical* (Jan. 8, 2018).[3] In Calendar Year 2018, CMS estimates that an average of 59.1 million people will have received benefits under Parts A and B each month. Centers for Medicare & Medicare Servs., *CMS Fast Facts: CMS Program Data - Populations* (July 2018).[4]

With its growth, the Medicare program has become "a massive, complex health and safety program * * * embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations." *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). And its administration is difficult. "Over the years, HHS and CMS have come to appreciate their roles as regulatory and procurement agencies when it comes to the administration of the Medicare program. But the history of the program suggests that HHS and CMS did not come easily to this realization." *See* Eleanor D. Kinney, *The Accidental Administrative Law of the Medicare Program*, 15 Yale J. Health Policy, L. & Ethics 111, 138 (2015). Today, Medicare is "governed by a complex web of legislative rules, interpretive rules and manuals, policy guidance and computer pro-

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[2] *Available at* https://bit.ly/2BTku4o.

[3] *Available at* https://go.cms.gov/1Jy5kin.

[4] *Available at* https://go.cms.gov/1JjCGaC.

grams" that "guide a host of decisions" concerning the program's operations. *Id.* at 111. As a result, even seemingly small tweaks to a subcomponent of the Medicare program can have far-reaching consequences.

2. The saga of the policy at issue here—whether Part C managed-care patients should be counted as entitled to benefits under the Part A fee-for-service component of the Medicare program—exemplify why Congress wanted public input on all substantive standards. The DSH adjustment is just one part of the constantly changing and "byzantine process" that governs Medicare payments to hospitals. *Billings Clinic* v. *Azar*, 901 F.3d 301, 309-311 (D.C. Cir. 2018); *accord Schweiker* v. *Gray Panthers*, 453 U.S. 34, 43 (1981) (describing the Medicare program as "Byzantine" and "among the most intricate ever drafted by Congress."). Similarly "byzantine" is the process for determining the "Medicare and Medicaid fractions" used to "provide a proxy for the total low-income patient percentage" when calculating the DSH adjustment itself. *Catholic Health Initiatives Iowa Corp.* v. *Sebelius*, 718 F.3d 914, 916 (D.C. Cir. 2013). "Many aspects of the DSH adjustment have been challenged over the years," *see id.* at 917, as would be expected given this complexity and the Government's shifting understanding of that legal landscape.

Whether Part C days are included in the Medicare or Medicaid fraction may *seem* like a minor issue. But it has far-reaching effects. As Petitioner stressed in its bid for this Court's review, the status of Part C days implicates $3 to $4 billion in Medicare spending that supports the work of hospitals that disproportionately serve vulnerable populations. *See*

Pet. 14. And for the individual hospitals whose funding turns on that determination, "the practical consequences of this dispute number in the hundreds of millions of dollars." *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 5 (D.C. Cir. 2011); *accord Allina Health Servs.* v. *Sebelius*, 746 F.3d 1102, 1107 (D.C. Cir. 2014) (observing the "enormous financial consequences for the hospitals"). The effects go far beyond the financial, however, as that funding translates directly into a wide range of critical services for low-income patients. Given these effects, the determination to include Part C days in the Medicare or Medicaid fraction calls out for notice and comment like any other major policy change.

Petitioner argues that upholding the decision below would mire the Medicare system in red tape by subjecting every CMS decision to notice and comment. Pet. Br. 41-43. That concern is overblown, as we explain below. *Infra* pp. 19-22. Petitioner's true motive instead is to seek a special rule that allows CMS to avoid the DSH-adjustment payments due by changing a substantive legal standard governing the payment calculation without advance notice and comment. By recharacterizing as mere suggestions CMS's mandates to Medicare contractors, hospitals, and the Provider Reimbursement Review Board (PRRB), and then disclaiming Section 1395hh(a)(2)'s purportedly burdensome and unworkable notice-and-comment procedures, Petitioner is trying to escape CMS's payment obligations. The Court should not allow that to happen.

3. Notice and comment is not just the law. It also improves policy outcomes. This Court has long recognized that "fairness and deliberation" should

undergird any "administrative action with the effect of law." *United States* v. *Mead Corp.*, 533 U.S. 218, 230 (2001).

Notice and comment is the principal way "to assure due deliberation." *Smiley* v. *Citibank (S. Dakota), N.A.*, 517 U.S. 735, 741 (1996). And it serves two central purposes. First, providing for notice and comment directs the regulatory process "to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies." *National Elec. Mfrs. Ass'n* v. *EPA*, 99 F.3d 1170, 1174 (D.C. Cir. 1996) (quoting *MCI Telecomms. Corp.* v. *FCC*, 57 F.3d 1136, 1141 (D.C. Cir. 1995)). Second, notice and comment "promot[es] informed agency action" by making sure that "'the agency will have before it the facts and information relevant to a particular administrative problem.'" *Id.* (quoting *MCI Telcomms.*, 57 F.3d at 1141). By guaranteeing both public participation and informed agency action, the notice-and-comment requirement works toward a better administrative process for all.

To be sure, the notice-and-comment process may require that agencies invest greater time and deliberation than they may otherwise be inclined to do. But in the Medicare context and outside of it, "[p]re-adoption notice-and-comment can be most helpful for significant guidance documents that are particularly complex, novel, consequential, or controversial." *See* Office of Mgmt. and Budget, Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3438 (Jan. 25, 2007). And when "controlling effect" is given to agency conduct setting a substantive legal standard on issues of sufficient "importance," such rules should "be promulgated only following public

participation." Kevin W. Saunders, *Interpretative Rules with Legislative Effect: An Analysis and A Proposal for Public Participation*, 1986 Duke L.J. 346, 383 (1986).

Notice and comment helps not just the public, but also the courts. Just as notice and comment allows "the public * * * a chance to speak and be heard," it allows a reviewing court to assess whether "the public [was] *listened* to" and whether "its evidence and point of view" were considered. Eugene Scalia, Essay, *The Value of Public Participation in Rulemaking*, Penn. Reg. Rev. (Sept. 25, 2017) (emphasis in original).[5] That enables the federal courts to provide a meaningful check on administrative conduct and inject another layer of accountability into the process, which is critical to our constitutional framework. *See FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 536 (2009) (Kennedy, J., concurring) (explaining the importance of judicial review given "the administrative agency's unique constitutional position" as "the exact locus of its powers present questions that are delicate, subtle, and complex").

The Medicare program, too, benefits from notice and comment. By refusing to allow public participation on the challenged policy concerning the treatment of Part C patients in the Medicare and Medicaid fractions, CMS deprived itself and the public of the benefits of these statutorily mandated procedural protections. Indeed, had CMS opened up the decisionmaking process to public scrutiny rather than "pull a surprise switcheroo," *Allina Health Servs.*,

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[5] *Available at* https://bit.ly/2fKUoZk.

746 F.3d at 1108 (quoting *Environmental Integrity Project* v. *EPA*, 425 F.3d 992, 994 (D.C. Cir. 2005)), Respondents' resort to this torturous litigation may never have been necessary. When it works as intended, notice and comment catches mistakes before they are made. Without it—as here—it can lead to over a decade of litigation.

II. PETITIONER'S NEW POLICY ON PART C DAYS CHANGES A SUBSTANTIVE LEGAL STANDARD AND THEREFORE REQUIRED NOTICE AND COMMENT.

Petitioner argues that CMS's calculation of the so-called Medicare fraction—a portion of the formula that determines the DSH payment given to hospitals serving the most-vulnerable populations—did not require notice-and-comment rulemaking because it was merely a "nonbinding interpretation of a statute." *See* Pet. Br. 20-41. That litigation position is not only contrary to the Medicare Act, as described above, it is also at odds with the APA, and the contemporaneous views of CMS's own officials.

Further, it is contrary to the government's—including the current Administration's—view of the line between interpretive and legislative rules outside the Medicare context. The Department of Justice and other federal agencies have concluded that rules that create, define, and regulate the rights, duties, and obligations of parties—whatever their label—are substantive legal standards and must be subjected to notice and comment. CMS could not include Part C days in the Medicare fraction without first going through notice and comment.

A. Section 1395hh(a)(2) Required Notice and Comment Here.

1. Petitioner contends that Congress in Section 1395hh(a)(2) actually imported the APA, including its interpretive-rule exemption for notice and comment. Pet. Br. 22-28. But three different canons of construction counsel against that conclusion.

First, Congress did not import or cross-reference the APA's interpretive-rule exemption in Section 1395hh(a)(2). *Cf.* 42 U.S.C. § 7607(d) (stating that the Clean Air Act's rulemaking provisions "shall not apply in the case of any rule or circumstance referred to" in the APA's interpretive-rule exception). Congress "knew how to distinguish between regulations that have the force and effect of law and those that did not, but chose not to do so in" Section 1395hh(a)(2). *Department of Homeland Sec.* v. *MacLean*, 135 S. Ct. 913, 921 (2015).

Second, Petitioner's argument would result in Section 1395hh(a)(2)'s rulemaking provision meaning the exact same thing as the APA's, despite using different language. Yet the Court "refrain[s] from concluding * * * that the differing language * * * has the same meaning." *Russello* v. *United States*, 464 U.S. 16, 23 (1983).

Finally, the APA provides the "default" rules when an agency's organic act does not provide specific ones. *See National Petrochemical & Refiners Ass'n* v. *EPA*, 643 F.3d 958, 961 (D.C. Cir. 2011) (Brown, J., dissenting from denial of rehearing en banc) (noting the "default notice-and-comment procedures of the APA"). If Section 1395hh(a)(2) were to mean the exact same thing as the APA's rulemaking provision, then Congress would have had no reason to pass

Section 1395hh(a)(2). And this Court "requir[es] a change in language to be read, if possible, to have some effect." *American Nat'l Red Cross* v. *S.G.*, 505 U.S. 247, 263 (1992). Reading Section 1395hh(a)(2) to be congruent with the APA would make Congress's amendment adding the section a nullity.

2. For more than seventy years, the APA has governed federal agencies engaging in rulemaking. 60 Stat. 237 (1946). Under the APA, agencies must provide a public notice-and-comment period to "give interested persons an opportunity to participate in the rule making [process] through submission of written data, views, or arguments." 5 U.S.C. § 553(c). The APA distinguishes between "substantive" or "legislative" rules and "interpretive" rules. Generally speaking, promulgating "legislative" rules requires notice and comment, while "interpretive" rules do not. *Compare id.*, *with id.* § 553(d). But the APA does not define the difference between the two.

Despite decades of case law, the distinction between "legislative" and "interpretive" rules remains muddled. The "precise meaning" of the "term 'interpretative rule,' or 'interpretive rule,'" has been "the source of much scholarly and judicial debate." *Perez* v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (declining to "wade into that debate"). The line is one that "'breeds bewilderment and frustration'" and has variously been called "'fuzzy,' 'tenuous,' 'baffling,' 'blurred,' and 'enshrouded in considerable smog'" by courts and commenters alike. *See* Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. Chi. L. Rev. 1705, 1708-09 (2007) (citations and footnotes omitted).

Congress enacted the Medicare Act's distinct notice-and-comment requirements—which direct HHS to engage in notice-and-comment rulemaking for any "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing * * * payment for services"—against this backdrop. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4035(b). Congress was concerned that "important polices [were] being developed without benefit of the public notice and comment period." H.R. Rep. No. 100-391, at 430 (1987).

So rather than rely on an amorphous distinction between legislative and interpretative rules, Congress laid down a bright line: *Any* HHS action—even one that is a mere "statement of policy"—that "establishes or changes a substantive legal standard" in the enumerated areas must go through notice and comment. *See* 42 U.S.C. § 1395hh(a)(2). Section 1395hh(a)(2)'s text reflects that congressional decision, declining to incorporate the APA's broad exemption for interpretative rules. *See* Pet. App. 12a.

Under the proper Section 1395hh(a)(2) standard, CMS's inclusion of Part C days in the Medicare fraction had to go through notice and comment. As the D.C. Circuit explained, CMS's inclusion of Part C days in the Medicare fraction was a "requirement" because CMS's contractors are required to use the fraction that CMS calculates when making DSH payment decisions. Pet. App. 12a. CMS's inclusion of Part C days in the fraction is also a change in standards because CMS previously *excluded* Part C days from the Medicare fraction. *Id.* at 13a. And CMS's inclusion of Part C days in the Medicare fraction is a substantive legal standard because it

"define[s] the scope of hospitals' legal rights to payment for treating low-income patients." *Id.* at 14a. The D.C. Circuit correctly concluded that CMS's inclusion of Part C days in the Medicare fraction had to undergo notice and comment.

3. Petitioner's contention that CMS's calculation of the Medicare fraction was merely nonbinding guidance falls all-the-more flat because CMS's own Provider Reimbursement Review Board (PRRB) understood the policy to bind it, not merely guide it.

The PRRB is an independent administrative forum that hears disputes concerning final reimbursement determinations made by CMS or by Medicare contractors. *See* 42 C.F.R. pt. 405, subpt. R; 42 U.S.C. § 1395oo(a); Pet. App. 25a. The PRRB is required to apply the Medicare Act, agency regulations, and CMS rulings. *See* 42 C.F.R. § 405.1867. But the PRRB need not follow "interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice." *Id.*

The PRRB can authorize expedited judicial review—allowing the appellant to skip over the PRRB portion of the Medicare appeals process—when "[t]he Board lacks the authority to decide a specific legal question" because it challenges "the substantive or procedural validity of a regulation or CMS ruling." *Id.* § 405.1842(f)(1)(ii). In other words, if the appellant's challenge goes to the validity of a substantive standard, the PRRB itself can authorize the appellant to bypass the Board's review. *See id.*

Here, in granting expedited judicial review of whether CMS's 2012 DSH calculations were procedurally invalid, the PRRB found it was bound by the vacated 2004 rule incorporating Part C patient days

as part of the Medicare fraction. Pet. App. 57a, 72a; *see also* Resp. Br. 16-17. The PRRB understood that "it is *bound* by the *regulation*," regardless of whether the regulation itself was "valid." Pet. App. 57a, 72a (emphases added). And what the Board did *not* say is equally important: had it viewed the decision as a nonbinding "interpretive rule" or "statement of policy," as Petitioner asserts it should have, the Board would have considered CMS's calculations but been free to deviate from them.

Importantly, the PRRB also granted expedited judicial review based upon its determination that it was "without the authority to decide the legal question of whether the regulation regarding the treatment of Medicare Part C days is valid and whether the Secretary's actions * * * are legal." *Id.* Simply put, the PRRB concluded that it did not have authority to determine the legality of the agency's action following vacatur of the 2004 rule.

The PRRB's decision to grant expedited judicial review cannot be squared with Petitioner's made-for-litigation assertion that CMS had issued a "nonbinding interpret[ive]" standard only. Rather, the record belies that assertion. Not only were Respondents' arguments before the PRRB uncontested, the intermediary on the other side of Respondents' appeal did not oppose expedited review. *Id.* Further, the D.C. Circuit held that the PRRB properly concluded that expedited judicial review was warranted (Pet. App. 10a-11a), and Petitioner has not contested that finding in this Court. Thus, as the case comes to this Court, CMS's own independent adjudicators correctly determined that the inclusion of Part C days in the Medicare fraction was a binding standard.

That conclusion dramatically undercuts Petitioner's argument that the PRRB could have come to its own conclusion as to whether Part C days were properly included. This Court declines to credit agency litigating positions that are "wholly unsupported * * * by administrative practice," *Bowen* v. *Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988), and that are a "*post hoc* rationalization advanced by an agency seeking to defend past agency action against attack." *Christopher* v. *SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012) (citation, internal quotation marks, and brackets omitted). It should do so again and reject Petitioner's argument that the PRRB could have rejected CMS's inclusion of Part C days in the Medicare fraction.

4. Petitioner's contention that CMS's inclusion of Part C days in the Medicare fraction was merely a nonbinding interpretation is further undercut by the Government's own warnings against slapping the "interpretive" label on substantive legal standards.

The Office of Management and Budget in 2007 issued a best-practices document cautioning that "[e]xperience has shown" that interpretive documents "may be poorly designed or improperly implemented," and these "documents may not receive the benefit of careful consideration accorded under the procedures for regulatory development and review," including notice and comment. 72 Fed. Reg. at 3432. As the D.C. Circuit has summarized the typical offending pattern: "Congress passes a broadly worded statute. The agency follows with regulations * * *. Then as years pass, * * * the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation." *Appa-*

lachian Power Co. v. *EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000).

That creation of substantive legal standards without advance notice and comment comes with serious consequences. As OMB further warned, "[c]oncern about whether agencies are properly observing the notice-and-comment requirements * * * has received significant attention. The courts, Congress, and other authorities have emphasized that rules which do not merely interpret existing law or announce tentative policy positions but which establish new policy positions that the agency treats as binding must comply with the APA's notice-and-comment requirements, regardless of how they initially are labeled." 72 Fed. Reg. at 3433; *see also* Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals and the Like-Should Federal Agencies Use Them to Bind the Public?*, 41 Duke L.J. 1311 (1992); 72 Fed. Reg. at 3432 n.2.

Just this past year, the Department of Justice announced its own position that "interpretations" such as the one at issue here require notice and comment. The Attorney General cautioned in a November 2017 memorandum that "the Department has in the past published guidance documents—or similar instruments of future effect by other names, * * * —that effectively bind private parties without undergoing the rulemaking process." Mem. from Att'y Gen., U.S. Dep't of Justice 1 (Nov. 16, 2017).[6] He then announced that "[t]he Department will no longer engage in this practice. Effective immediately, Department components may not issue guidance docu-

[6] *Available at* https://bit.ly/2E2otkb.

ments that purport to create rights or obligations binding on persons or entities outside the Executive Branch." *Id.*

These problems with substantive standards adopted without notice and comment are precisely the ones Congress intended to solve when it enacted Section 1395hh(a)(2). When a policy such as the one offered by CMS here effectively binds regulated parties and agency officials alike, the agency must first go through proper notice-and-comment channels. Petitioner's attempt to relabel its policy a "nonbinding interpretation" is simply another instance of a rule masquerading as a guidance document. The Court should not countenance it.

B. The Government's Workability Concerns Are Overblown.

Petitioner contends that an "interpretation of Section 1395hh" giving effect to the statute's plain language "would substantially undermine HHS's ability to administer Medicare in a workable manner." *See* Pet. Br. 41-43. But Petitioner's administrability concerns are overblown. Not all CMS policies need go through notice and comment; just those, like the determination here, that substantively alter how providers are paid.

1. CMS need not engage notice and comment for true guidance documents that do not tie the hands of the agency or the PRRB. For instance, Petitioner frets that a ruling for Respondents will upend the Provider Reimbursement Manual. Pet. Br. 41-42. But this Court and others have repeatedly concluded that the Manual is merely an interpretive guide that does "not have the force and effect of law." *See, e.g.*, *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 99

(1995); *South Shore Hosp., Inc.* v. *Thompson*, 308 F.3d 91, 103 (1st Cir. 2002); *National Med. Enters.* v. *Bowen*, 851 F.2d 291, 293 (9th Cir. 1988); *see also Trust Under Will of Wills* v. *Burwell*, 306 F. Supp. 3d 684, 693 (E.D. Pa. 2018) (holding that comparative-volume consideration in a CMS Survey & Certification Memorandum provided only "some form of guidance as to how the legal standards are applied" when "the agency maintains the same authority to grant or deny applications as it would without a stated public policy"). The decision below does not challenge these consistent holdings.

CMS generally also need not put its policies through notice and comment when they can be disregarded by agency adjudicators like the PRRB. The PRRB can—and does—routinely reject CMS guidance as inconsistent with the Medicare Act or HHS regulations. *See, e.g.*, *Provena Health 2006 LIP SSI Percentage Calc. Grp.* v. *National Gov't Servs., Inc.*, No. 09-0939GC, 2015 WL 10371518, at *5 (PRRB Dec. 30, 2015); *Health All. Hospital Leominster, Mass.* v. *BlueCross BlueShield Ass'n/NHIC Corp.*, No. 06-0984, 2013 WL 11261923, at *7 (PRRB Sept. 24, 2013); *LAC ESRD Pre-Composite Rate Grp.* v. *BlueCross BlueShield Ass'n/Blue Cross of Cal.*, No. 92-0110G, 1999 WL 766795, at *9 (PRRB Sept. 21, 1999). When the PRRB can and does reject a CMS determination, that is strong evidence that the determination does not bind the agency and thus is not a "requirement" under Section 1395hh(a)(2). But those instances stand in stark contrast to the Medicare-fraction determination challenged here, which the PRRB understood to bind it. *See supra* pp. 15-16.

2. Tellingly, Petitioner's administrability fears have not materialized in the D.C. Circuit. The D.C.

Circuit in applying the decision below has not applied a blanket rule that all Medicare administrative materials issued by HHS and CMS now require notice and comment, as the Petitioner apparently fears. The D.C. Circuit has held that instructions in the Medicare Claims Processing Manual issued by CMS "do not alter the applicable legal standards" when those instructions "set forth an enforcement policy" only. *Clarian Health*, 878 F.3d at 354-356. The D.C. Circuit observed that, unlike the Part C days DSH policy here, "the agency maintains the same authority * * * that it had prior to the adoption of the Manual instructions" and the instructions neither "change the legal standards that govern the hospitals" nor "change the legal standards that govern the agency" because "the instructions bind neither CMS nor the Board in adjudications." *Id.* That is exactly right. And it confirms that CMS can operate under the test adopted below.

If anything, Medicare's regulatory process may run *more* efficiently under Section 1395hh(a)(2)'s relatively clearer "substantive legal standards" test. The uncertainty about when notice and comment is required under the APA's legislative–interpretive dichotomy, *supra*, pp. 13-14, pervades rulemaking challenges. "Even by the standards of administrative law—a field in which uniform, predictable rules of black-letter law are hard to come by—the resulting litigation is considered notoriously difficult." David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 Yale L.J. 276, 278 (2010). The D.C. Circuit's standard, under which notice and comment are required when the agency policy would change a substantive legal standard affecting the rights, duties, and powers of

regulated parties (Pet. App. 12a-14a), is more-definitive, providing more guidance to CMS policy-makers than the APA's amorphous tests and better aligned with the text of the Medicare statute. But at the very least, it will not grind the machinery of the Medicare system to a halt.

CONCLUSION

For the foregoing reasons, as well as those in Respondents' brief, the D.C. Circuit's judgment should be affirmed.

Respectfully submitted,

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IN THE

Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

ALLINA HEALTH SERVICES, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF *AMICI CURIAE* AMERICAN MEDICAL ASSOCIATION AND MEDICAL SOCIETY OF THE DISTRICT OF COLUMBIA IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICI CURIAE*[1]

Amici are private, voluntary, nonprofit organizations of physicians dedicated to promoting the public welfare through the maintenance of the highest professional standards and the provision of quality healthcare.

Amicus the American Medical Association (AMA) is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty area and in every state.

Amicus the Medical Society of the District of Columbia (MSDC) is part of the federation of state, county, and specialty medical societies that constitute the AMA. With over 2,500 members, the MSDC is the largest medical organization representing metropolitan Washington physicians in the District. Since 1817, the MSDC has been supporting and advocating for patients, physicians, the medical profession, and the betterment of public health.

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae* and their counsel, made any monetary contribution toward the preparation and submission of this brief. Pursuant to Rule 37.3, petitioners and respondents have consented to the filing of this *amici curiae* brief.

The AMA and MSDC join this brief on their own behalves and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

This case concerns the scope of HHS's obligation to engage in notice-and-comment rulemaking when adopting rules concerning provider reimbursement in the Medicare program. *See* 42 U.S.C. § 1395 *et seq.* As petitioner recognizes, the HHS action at issue here has a substantial financial impact on both hospitals and the public fisc. *See* Pet. 23; Pet. App. 4a. Yet HHS took the challenged action without prior notice to the medical community and without any opportunity for public comment. Through its retroactive effect, HHS's action created unfairness and disrupted settled financial expectations of healthcare providers. Moreover, because neither healthcare providers nor any other member of the public had an opportunity to weigh in, the rule was not informed by the practical insights that stakeholders can provide, or the policy concerns of all those throughout the nation who are affected by Medicare spending.

Although the physician members of the AMA and MSDC are not subject to this particular rule, they are substantially affected by other HHS rules and practices concerning Medicare reimbursements of physicians. When HHS engages in notice-and-comment processes concerning Medicare reimbursements for physicians, *amici* are consistent and active participants, who have successfully prevailed on HHS to modify its regulatory policy. The AMA and the MSDC thus have a strong interest in

ensuring that HHS's rulemaking regarding Medicare reimbursement is conducted in a fair, transparent, and fully informed way. Moreover, the medical associations can offer real-world knowledge of the conditions and circumstances of providing healthcare pursuant to Medicare regulations, and participating in the Medicare regulatory process, that will be useful to the Court's analysis.

SUMMARY OF ARGUMENT

Medicare pays for 20 percent of healthcare in the United States.[2] Medicare benefits paid in Fiscal Year 2017 amounted to nearly $700 billion, and Medicare payments to physicians in Calendar Year 2016 exceeded $100 billion.[3] For physicians, Medicare represents an important source of income: In 2016, among physicians other than pediatricians, 96 percent reported that they saw at least some patients who are covered by Medicare—and 9.6 percent of all physicians reported that more than half of their patients were covered by Medicare.[4] Because of the major role that Medicare plays in paying for American healthcare, HHS's actions concerning Medicare reimbursements

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[2] *See* Ctrs. for Medicare & Medicaid Servs., *National Health Expenditures 2017 Highlights* 2, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf (last visited Dec. 18, 2018).

[3] *See* Ctrs. for Medicare & Medicaid Servs., *Fast Facts*, https://www.cms.gov/fastfacts/ (last updated Aug. 1, 2018).

[4] *See* Kurt D. Gillis, *Policy Research Perspectives: Physicians' Patient Mix—A Snapshot from the 2016 Benchmark Survey and Changes Associated with the ACA* 3 & n.4 (2017), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/health-policy/PRP-2017-physician-benchmark-survey-patient-mix.pdf.

have an outsized effect on physicians and other healthcare providers.

As this case illustrates, discrete changes in HHS's Medicare reimbursement actions can have enormous effects on providers. This case concerns the method HHS used to calculate the "Medicare fraction," which is used in determining the "disproportionate share hospital" payment that hospitals receive for the additional costs they incur in providing services to low-income patients. *See* Br. for Resp'ts 8-9. According to HHS's own estimation, how the Medicare fraction is calculated has a huge financial impact on both hospitals and the government—implicating between $3 and $4 billion in Medicare reimbursements over nine years. Pet. 23; *see also* Pet. App. 23a ("The financial impact on the hospitals of this seemingly minor detail is in the hundreds of millions of dollars.").

The dispute in this case centers on whether HHS was required under the Medicare statute—specifically, 42 U.S.C. § 1395hh(a)(2) or (a)(4)—to use notice-and-comment rulemaking in setting forth its method for calculating hospitals' Medicare fraction. The court of appeals held that notice-and-comment rulemaking was required, because (among other things) HHS's calculation method is a "rule, requirement, or other statement of policy" that changes a "substantive legal standard" governing "payment for services." Pet. App. 12a-14a (quoting § 1395hh(a)(2)).

HHS takes the position that "the challenged action here is not 'a rule, requirement, or other statement of policy,'" Br. for Pet'r 39 (quoting 42 U.S.C. § 1395hh(a)(2)), because it is said not to have any "'future effect,'" *id.* (quoting 5 U.S.C. § 551(4)). "To the contrary," HHS asserts, "the agency in theory would remain free to calculate the fractions in other years

(between 2004 and 2013, at least, when no binding regulation was in effect) based on a different nonbinding interpretation of the statute, if it chose." *Id.* at 39-40. Were the law otherwise, HHS says, it "would jeopardize the flexibility" that HHS declares to be "essential" to its administration of Medicare. *Id.* at 42. In HHS's words, "[t]he notice-and-comment process can be 'long and costly' and 'often requires many years and tens of thousands of person hours to complete,'" and requiring notice-and-comment would accordingly have a "disruptive effect" on the Medicare program. *Id.* (quoting Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretative Rules*, 52 Admin. L. Rev. 547, 550-51 (2000)).

Amici do not here respond to HHS's statutory analysis, which is amply addressed by respondents. Nor do *amici* weigh in on the proper method of calculating the "Medicare fraction," which does not apply to reimbursements for physician services and thus does not directly affect *amici*'s member physicians.

Instead, *amici* write to respond to HHS's general statements regarding the costs and burdens of notice-and-comment rulemaking in the Medicare program. What HHS's brief does not recognize is that HHS's failure to adopt prospective, generally applicable rules—and its failure to permit the public to weigh in on how the agency administers Medicare through notice-and-comment—can impose substantial costs and burdens on the providers and beneficiaries who participate in the Medicare program. *Amici* write to inform the Court of the real-world implications that follow when HHS forgoes notice-and-comment procedures when changing its approach to Medicare reimbursements.

The many physicians and patients who rely on Medicare are entitled to clear and certain rules so they will know which services are covered and whether there are special requirements governing how those services are to be performed. Generally applicable, prescriptive regulations accomplish this—but informal decision-making does not.

Given the immense stakes of Medicare reimbursement, clarity and consistency are paramount. As this case well demonstrates, even "seemingly minor" modifications in reimbursement determinations give rise to extreme financial consequences for providers, and ultimately their patients. And the effect of changes in Medicare reimbursements does not just change the dollar amounts to which providers are entitled. After all, physicians can be held liable—including criminally liable—under the False Claims Act if they fail to follow the rules when submitting Medicare claims, so it is imperative that they be able to ascertain what those rules are.

Moreover, clarity and transparency in Medicare rulemaking is equally if not more important to the general public, including patients. The number of healthcare dollars available for Medicare is large, but it is not infinite. The public has a right to know and weigh in on how the money is spent. If HHS determines that treatment for one medical condition or procedure will be reimbursed, but another will not, the agency should articulate why. Patients' health is at stake—and HHS must be transparent in its decision-making process.

While HHS may find notice-and-comment rulemaking burdensome, the notice-and-comment process is not an "arbitrary hoop[] through which federal agencies must jump without reason." *Sprint*

Corp. v. FCC, 315 F.3d 369, 373 (D.C. Cir. 2003). Instead, "[t]he essential purpose of according . . . notice and comment opportunities is to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies." *Batterton v. Marshall*, 648 F.2d 694, 703 (D.C. Cir. 1980). Notice-and-comment rulemaking facilitates public input into agency decision-making, as well as greater transparency and clarity on the part of the agency—and in this way provides an important check against unbridled administrative power. Because the administration of Medicare implicates the health of millions of Americans, fulsome opportunities for public input are essential.

ARGUMENT

I. NOTICE-AND-COMMENT RULEMAKING PROMOTES FAIRNESS AND PUBLIC PARTICIPATION IN REGULATORY OVERSIGHT.

A. Prospective Rulemaking Through Notice-And-Comment Promotes Consistency And Clarity.

The benefits of prospective, notice-and-comment rulemaking are well recognized. The promulgation of prospective rules through notice-and-comment rulemaking "ensures fairness to affected parties" in two important ways. *Sprint Corp.*, 315 F.3d at 373 (quoting *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 547 (D.C. Cir. 1983)). First, prospective rulemaking gives parties advance notice so they can conform their conduct according to settled expectations. "Elementary considerations of fairness dictate that individuals should have an opportunity to know what the law is and to conform their conduct

accordingly." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994). The notice-and-comment process promotes such fairness by "informing affected parties and affording them a reasonable time to adjust to the new regulation." *Am. Fed'n of Gov't Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981).

The comment procedures also promote another "essential component" of fairness: They give affected parties "the opportunity to be heard" regarding the rules they will be subject to. *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 547 (citing *Nat'l Ass'n of Home Health Agencies v. Schweiker*, 690 F.2d 932, 949 (D.C. Cir. 1982)). To the extent agency action threatens the rights and interests of a regulated party, basic fairness dictates that the party "be given a chance to present their case to the [agency] before [it] acts." *Schweiker*, 690 F.2d at 949 (describing this as "the fairness element" of the Administrative Procedure Act's notice-and-comment procedures).

For these reasons, prospective rulemaking via notice-and-comment "is generally a 'better, fairer, and more effective' method of implementing a new industry-wide policy than is the uneven application of conditions in isolated" adjudications. *Cmty. Television of S. Cal. v. Gottfried*, 459 U.S. 498, 511 (1983). "Making policy through adjudication can lead to inconsistent outcomes and frustrates expectations when policy changes retroactively. Making policy through rulemaking is much more likely to result in standards that apply prospectively, providing clear notice of the law's requirements to all concerned." Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 Harv. L. Rev. 467, 546 (2002); *see also* Kenneth Culp Davis, *Discretionary Justice* 66 (Univ. of Ill. Press 1971) (1969) (due to the "unfair[ness]" of retroactive

application, "prospective rules often should be preferred to retroactive law-making through adjudication").

B. Notice-And-Comment Rulemaking Permits Democratic Participation And Oversight Of The Agency.

Prospective rulemaking also achieves the important purpose of giving affected parties and the public the opportunity to weigh in on important policy debates. *Schweiker*, 690 F.2d at 950. Congress enacted the notice-and-comment procedures in the Administrative Procedure Act (APA) for precisely that reason: "to give the public an opportunity to participate in the rule-making process." *Texaco, Inc. v. Fed. Power Comm'n*, 412 F.2d 740, 744 (3d Cir. 1969); *Am. Fed'n of Gov't Emps.*, 655 F.2d at 1157–58 (noting the "congressionally-mandated policy of affording public participation that is embodied in [the APA's notice-and-comment procedures]"). Congress believed that, "due to the unrepresentative nature of an administrative agency, 'public participation . . . in the rulemaking process is essential in order to permit administrative agencies to inform themselves, and to afford safeguards to private interests.'" *Batterton*, 648 F.2d at 703 n.47 (quoting S. Doc. No. 248, 79th Cong., 2d Sess. 19–20 (1946)).

Public participation in rulemaking is essential for several reasons. First and foremost, "public participation assures that the agency will have before it the facts and information relevant to a particular administrative problem, as well as suggestions for alternative solutions." *Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 662 (D.C. Cir. 1978). Specifically, "[n]otice and comment gives interested parties an opportunity to participate through the submission of data, views and

arguments." *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 12–13 (D.D.C. 2004). This exchange of information "enables the agency promulgating the rule to educate itself before establishing rules and procedures which have a substantial impact on those regulated." *Texaco*, 412 F.2d at 744.

Second, and relatedly, public rulemaking "increase[s] the likelihood of administrative responsiveness to the needs and concerns of those affected." *Guardian*, 589 F.2d at 662. After all, regulated entities and stakeholders are particularly likely to have "valuable information" regarding a proposed rule. *Schweiker*, 690 F.2d at 950 (noting that home health agencies would likely have valuable information and insight regarding a proposed rule because they "had been dealing with the various intermediaries and working with the Medicare system for years"). By requiring the agency to consider their viewpoints, public rulemaking ensures that agencies do not promulgate rules that "substantially affect private parties and resolve important issues without the beneficial input that those parties could provide." *Id.* And even if regulated entities and stakeholders ultimately disagree with the final rule, notice-and-comment procedures "tend[] to promote acquiescence in the result." *Guardian*, 589 F.2d at 662.

Of course, "[t]he more expansive the regulatory reach of the[] rule[], . . . the greater the necessity for public comment." *Am. Fed'n of Gov't Emps.*, 655 F.2d at 1156. And public rulemaking is especially important where, as here, "one can expect real interest from the public in the content of the proposed regulation." *Levesque v. Block*, 723 F.2d 175, 185 (1st Cir. 1983) (holding that notice-and-comment was required where "plaintiffs show[ed] interest in the content of the regulation, [and] many commentators

participated in the final rulemaking when given an opportunity"). *See also, e.g., Nat'l Nutritional Foods Ass'n v. Kennedy*, 572 F.2d 377, 385 (2d Cir. 1978) (holding that agency was required to use public rulemaking procedures because the agency's rule had extensive regulatory reach and the legislative history suggested that the public would be interested in the rule). Given the indisputable importance of the Medicare program, there can be no doubt that the public will want a say in how the nation's healthcare budget is directed. *See* Robert Pearl, *Healthcare is the No. 1 Issue for Voters; A New Poll Reveals Which Healthcare Issue Matters Most*, Forbes (Aug. 13, 2018, 7:53 AM), https://www.forbes.com/sites/robertpearl/2018/08/13/midterms/#12aa2ff73667.

II. THE USE OF NOTICE-AND-COMMENT RULEMAKING IMPROVES REGULATORY OUTCOMES.

These well-recognized benefits of notice-and-comment rulemaking processes apply with particular force in the context of Medicare reimbursement regulations. Prospective rulemaking via notice-and-comment is critical where, as here, the affected parties face the risk of civil penalties and even criminal liability if they fail to comply with an agency's rules. Moreover, in light of the signal importance of healthcare and Medicare coverage to the American economy, preserving opportunities for public oversight of the Medicare program is critical.

With its single-minded focus on the burdens of notice-and-comment rulemaking, HHS all but ignores the other side—both the costs that are imposed on Medicare providers and beneficiaries when Medicare policy is conducted without opportunity for public comment, and the important benefits that accrue

when the public participates in the development of regulatory policy.

A. When HHS Has Failed To Use Notice-And-Comment Rulemaking, Unfairness And Confusion Have Resulted.

To demonstrate the real-world stakes of HHS's regulatory practices, *amici* describe below two examples where HHS's failure to engage in notice-and-comment rulemaking, and its failure to provide clear and generally applicable rules, have led to inconsistency and unfairness for providers and beneficiaries.

1. National Coverage Determinations Versus Local Contractor Actions.

A. The Medicare Act provides that no Medicare payment may be made to a physician under Medicare Part B if items or services are not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Thus, in order to obtain Medicare reimbursement, providers must make certifications relating to the services they have provided to patients—including a certification of medical necessity. *See* 42 U.S.C. § 1395f(a)(2)-(3) (Medicare payment "may be made only . . . if," *inter alia*, "a physician certifies that such services are required to be given"). In practical terms, when submitting Form CMS-1500 for payment under the Medicare program, a physician must certify via signature that, among other things, "the services on this form were medically necessary," and "I [the

provider] have familiarized myself with all applicable laws, regulations, and program instructions."[5]

HHS decides "whether a particular medical service is 'reasonable and necessary' . . . by promulgating a generally applicable rule or by allowing individual adjudication." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). The former course involves a National Coverage Determination (NCD). Through NCDs, HHS announces "whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B). As relevant here, NCDs are "nationwide, prospective, population-based policies that apply to clinical subsets or classes of Medicare beneficiaries and describe the clinical circumstances and settings under which particular services are reasonable and necessary (or are not reasonable and necessary)." 67 Fed. Reg. 54,534, 54,535 (Aug. 22, 2002). Under the current statute, HHS is required to use notice-and-comment procedures to promulgate NCDs—allowing at least 30 days for public comment before a final decision is made. 42 U.S.C. § 1395y(l)(3); *see also* 78 Fed. Reg. 48,164 (Aug. 7, 2013). NCDs are binding and have the force of law. *See* 42 C.F.R. § 405.1060.[6]

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[5] The form can be seen at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf. Ctrs. for Medicare & Medicaid Servs., OMB-0938-1197, *Health Insurance Claim Form*, https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (last revised Feb. 1, 2012).

[6] As respondents explain, at the time that the statute at issue here, 42 U.S.C. § 1395hh(a)(2), was enacted, NCDs were adopted without notice-and-comment—and NCDs were explicitly carved out of that section's notice-and-comment requirement. Br. for Resp'ts at 39-40. Given the importance of NCDs to provider reimbursement, however, Congress later adopted a separate notice-and-comment requirement for NCDs. *See* 42 U.S.C. § 1395y(l)(3).

In the absence of an NCD, whether services are reasonable and necessary is determined by local Medicare Administrative Contractors—*i.e.*, private entities with which HHS contracts to administer Medicare. A contractor may issue a Local Coverage Determination (LCD), which announces "whether or not a particular item or service is covered" by that particular contractor. 42 U.S.C. § 1395ff(f)(2)(B). By statute, LCDs are subject to a form of notice-and-comment, in that they must be published on the contractor's website for a minimum of 45 days before they become effective. 42 U.S.C. § 1395y(l)(5)(D). Otherwise, however, LCDs are different from NCDs because (a) they do not apply at all beyond the individual contractor that has adopted them, and (b) they are not binding on the agency. *See* 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003) (administrative law judge reviewing a contractor's claim denial "may consider, but [is] not bound by" the LCD in determining whether care is reasonable and necessary). If no NCD or LCD applies, contractors may also "make individual claim determinations, even in the absence of [a national or local coverage determination], . . . [B]ased on the individual's particular factual situation." *Id.*

B. In practice, LCDs are neither generally applicable regulations nor individual adjudications. Instead, they operate as uniform coverage decisions by the private insurers that serve as Medicare contractors. LCDs outline whether a particular private insurer will consent to allow Medicare reimbursement for treatments based on a collection of symptoms and indications taken out of the context of the individual patient's needs.

The reliance on these informal, regional, privately determined policies gives rise to adverse effects for

both physicians and patients. For one thing, it creates patchwork and inconsistent coverage that varies from region to region for Medicare beneficiaries. As the HHS Inspector General wrote, the use of LCDs means that Medicare "beneficiaries' access to items and services can depend on geography as much as their clinical indications." Office of the Inspector Gen., Dep't of Health & Human Servs., OEI-01-11-00500, *Local Coverage Determinations Create Inconsistency in Medicare Coverage* 9 (2014), https://oig.hhs.gov/oei/reports/oei-01-11-00500.pdf. "[B]eneficiaries in some States did not have access to items and services that had significant use among beneficiaries in other States," and "the likelihood that beneficiaries' items and services had coverage restrictions placed on them by LCDs varied widely by State." *Id.* at 9, 11. Moreover, these problems of inconsistency were not isolated to a handful of discrete procedures: to the contrary, "[o]ut of the 540 clinical topics addressed by LCDs, none were addressed by an LCD in every State—meaning that *every clinical topic was addressed in some States but not others.*" *Id.* at 11 (emphasis added).

By way of example, in 2008, Medicare patients with prostate cancer were eligible for a surgical treatment called CyberKnife if they lived in one of 33 states, but not if they lived in the other 17. *See, e.g.*, Stephanie Saul, *Geography Has Role in Medicare Cancer Coverage*, N.Y. Times (Dec. 16, 2008), https://www.nytimes.com/2008/12/17/health/policy/17knife.html. Thus, "Medicare will pay for a man's CyberKnife treatments in New Hampshire, but not across the border in Vermont"; "'[y]ou can live on one side of the street and get a procedure, but on the other side of the street you can't.'" *Id.* CyberKnife is in this way

"emblematic of the inconsistent way that the federal Medicare budget . . . is spent, region to region." *Id.*

Another adverse effect of reliance on LCDs is that—even though LCDs are deemed by HHS to be non-binding—physicians face grave risks by departing from LCDs. Recently, the government and/or *qui tam* relators have brought False Claims Act challenges against physicians arguing that billing Medicare for a service that is not medically necessary amounts to a fraudulent claim, and therefore subjects the physician to civil and/or criminal liability under the act. *See United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018); *United States v. Persaud*, 866 F.3d 371 (6th Cir. 2017); *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018). Some courts have treated LCDs as legally binding for purposes of liability under the False Claims Act: where a physician's treatment deviated from the LCD, the physician was found to have fraudulently billed Medicare. *U.S. ex rel. Ryan v. Lederman*, No. 04-2483, 2014 WL 1910096, at *4 (E.D.N.Y. May 13, 2014); *U.S. ex rel. Youn v. Sklar*, 273 F. Supp. 3d 889, 896 (N.D. Ill. 2017).

The case *United States ex rel. Ryan v. Lederman* is illustrative. The defendant, Dr. Lederman, performed radiation treatment and stereotactic radiosurgery to treat cancer. 2014 WL 1910096, at *1. The local contractor for his jurisdiction issued two LCDs (then called LMRPs) that defined "stereotactic radiosurgery" and listed eight conditions that would trigger coverage. *Id.* at *2. One of the LCDs noted that "treatment of below the neck of diseases such as lung carcinoma with stereotactic radiosurgery [was] considered investigational at [that] time." *Id.* The government alleged that Dr. Lederman had submitted claims for reimbursement for below-the-neck stereotactic radiosurgery claims—and argued that

because the local contractor's LCDs excluded below-the-neck stereotactic radiosurgery from coverage, Dr. Lederman's claims for reimbursement for such procedures were false as a matter of law.

In his defense, Dr. Lederman argued that HHS's own regulations establish that LCDs are not controlling and provide only "guidance" on procedure coverage. *Id.* at *4. The court rejected Dr. Lederman's argument, stating: "I do not believe . . . that LCDs are advisory or not authoritative. . . . (Put another way, 'guidance' can be mandatory.)" *Id.* In a confusing twist, the government offered another HHS guidance document that described the general role of LCDs in support of its view that LCDs are binding for reimbursement determinations. *Id.* at *4-5. (citing *Medicare Program, Procedures for Making National Coverage Determinations*, 64 Fed. Reg. 22,619, 22,621 (Apr. 27, 1999)). Accepting the government's argument, the court concluded that "[t]he passage [cited by the government] makes clear that LCDs are mandatory for areas they cover." *Id.* at *5.

C. This example underscores the need for clarity in the form of generally applicable notice-and-comment rulemaking where the government makes consequential policy determinations governing physicians. The issuance of an NCD provides unambiguous, consistent authority on which physicians and patients can rely. Moreover, proceeding through centralized notice-and-comment rulemaking facilitates the participation of groups that have useful insights to offer. Notice-and-comment rulemaking on national coverage for CyberKnife, for example, would allow the AMA, the American Urological Association, the Mayo Clinic, the private insurance industry, and the general public to weigh in

on whether this is an appropriate use of Medicare funds.

Without such authoritative regulatory action, physicians struggle to know when they are providing treatment in compliance with Medicare policies versus when they could be subject to a criminal charge. And coverage determinations lose the benefit of commentary from interested parties who can offer evidence of clinical effectiveness. *See* Office of the Inspector Gen., Dep't of Health & Human Servs., *Local Coverage Determinations, supra*, at 13 ("the State-by-State differences in coverage created by LCDs are contrary to the growing practice of evidence-based medicine"). This creates an unfair system for physicians and regulatory scheme that lacks public input.

2. The Two-Midnight Rule.

A. The definition of "inpatient" services offers another example where generally applicable rulemaking through notice-and-comment would provide much-needed clarity for providers and patients. The Medicare Act provides for payment of the costs of "inpatient" hospital stays under Medicare Part A. *See* 42 U.S.C. §§ 1395d, 1395ww. By contrast, outpatient treatment is covered under Medicare Part B. *See* 42 U.S.C. § 1395k. The difference is financially significant for patients. Among other things, if care is billed under Part A, Medicare pays the total qualifying cost after a patient deductible. For care under Part B, Medicare generally pays 80 percent of costs and the patient is responsible for the remaining 20 percent. 42 U.S.C. §§ 1395e, 1395l.

However, what qualifies as "inpatient" versus outpatient care is ambiguous. The term "inpatient" is not defined in the statute. Nor, for many years, was

"inpatient" defined by regulation; instead, HHS issued a variety of guidance documents purporting to clarify which patients qualify to be billed under Part A for inpatient hospital services as opposed to Part B for outpatient service. In 2013, HHS at last promulgated via notice-and-comment a rule addressing "inpatient" care: a patient's hospital stay is to be reimbursed as "inpatient" care under Part A if the patient is "formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner" 42 C.F.R. § 412.3(a). The regulation goes on to explain the circumstances in which a physician should admit a patient for inpatient care: "an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights." *Id.* § 412.3(d)(1). This has come to be known as the "two-midnight rule."

B. Unfortunately, the two-midnight rule created a host of questions and confusion. Many hospital stays that extend beyond two midnights are not reimbursed as "inpatient" admissions. The HHS Inspector General determined that in Fiscal Year 2014, nearly 750,000 hospital stays for Medicare beneficiaries that extended beyond two midnights were billed as outpatient stays. *See* Office of the Inspector Gen., Dep't of Health & Human Servs., OEI-02-15-00020, *Vulnerabilities Remain Under Medicare's 2-Midnight Hospital Policy* 12 (2016), https://oig.hhs.gov/oei/reports/oei-02-15-00020.pdf. As the Inspector General explained, this appeared to be the result of confusion generated by the two-midnight rule and HHS's other policies:

> A large number of long outpatient stays is somewhat unexpected because these stays likely met the 2-midnight policy's expected-length-of-stay requirement for inpatient admission, and

> providers have a financial incentive to admit beneficiaries as inpatients when possible. That providers did not admit these beneficiaries may indicate that other factors caused them to continue to bill for a large number of long outpatient stays. These factors may include an inability to safely discharge beneficiaries, delays in care, or confusion about the 2-midnight policy.

Id.

As the Inspector General also explained, the high number of long outpatient stays is troubling because it imposes significant financial burdens on patients. Beneficiaries in more than 350,000 outpatient stays incurred costs in excess of the inpatient deductible—*i.e.*, the most they would have paid if they had been deemed inpatients—because care billed under Medicare Part B is billed at "20 percent of Medicare's rate for each service, and there is no cap on the total amount [these beneficiaries] can be responsible for paying." *Id.* at 13. Beneficiaries in outpatient stays also incurred charges for self-administered drugs that would be covered for an inpatient stay. *Id.* And many beneficiaries in outpatient stays "fac[ed] substantial charges after they le[ft] the hospital," because Medicare pays for a skilled nursing facility (such as a rehabilitation facility) "only if a beneficiary had a hospital stay that included at least 3 nights as an inpatient." *Id.*

In short, the lack of regulatory clarity surrounding the two-midnight rule has given rise to "one of the brutal truths of Medicare policy: Patients can be hospitalized for days, can undergo exams and tests, can receive drugs—without ever officially being admitted to the hospital," which means they "can face higher payments for drugs and coinsurance, but the big-ticket item is nursing home care." Paula Span,

Under 'Observation,' Some Hospital Patients Face Big Bills, N.Y. Times (Sept. 1, 2017), https://www.nytimes.com/2017/09/01/health/medicare-observation-hospitals.html; *see also* Elliot Raphaelson, *Inpatient vs. Observation Status: The Difference Can Be Costly*, Chi. Trib. (Nov. 21, 2018, 4:20 PM), https://www.chicagotribune.com/business/sns-201811211100--tms--savingsgctnzy-a20181121-20181121-story.html ("Unfortunately, Medicare policies and hospital policies in this area are ambiguous. . . . The current practices don't protect patients at all."); *Barrows v. Burwell*, 777 F.3d 106 (2d Cir. 2015) (putative class action on behalf of Medicare beneficiaries, challenging Medicare reimbursement practices for hospital stays). Patients face financial risks that are outside their control. And physicians face risks as well, for if they "incorrectly" bill for inpatient services, they can be subject to False Claims Act liability.

C. Despite the well-recognized problems with the two-midnight rule, HHS has not engaged in any further notice-and-comment regulation on the topic of "inpatient" status since the adoption of its 2013 rule. Although the agency allowed for public comment then, it has not engaged in a fulsome notice-and-comment process since that time to allow stakeholders an opportunity to identify and propose solutions for the unintended consequences and remaining problems following the agency's regulation. Instead of addressing inpatient admissions through notice-and-comment rulemaking, HHS has limited its response to informal guidance documents and FAQ answers.[7]

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[7] *See* 83 Fed. Reg. 41,144, 41,506-10 (Aug. 17, 2018); Ctrs. for Medicare & Medicaid Servs., MM10080, *Clarifying Medical Review of Hospital Claims for Part A Payment* (May 16, 2017), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10080.pdf;

Moreover, other HHS policies—including increasing scrutiny of inpatient admissions through audits, as well as penalties for readmissions, which apply only to patients who were originally admitted as inpatients—have favored cost savings over objective patient care, and thereby exacerbated this problem. *See* Zhanlian Feng et al., *Sharp Rise in Medicare Enrollees Being Held in Hospitals for Observation Raises Concerns about Causes and Consequences*, 31 Health Aff. 1251, 1256-57 (2012). In light of HHS's failure to provide a clear resolution of the issue through notice-and-comment rulemaking, the AMA has pledged to "work with third party payers to establish a uniform definition of 'observation care,'" based on patient-focused factors. *See* Council on Med. Serv., Am. Med. Ass'n, *Defining "Observation Care" H-160.944* (2014), https://policysearch.ama-assn.org/policyfinder/detail/Defining%20Observation%20Care%20H-160.944?uri=%2FAMADoc%2FHOD.xml-0-758.xml (last visited Dec. 18, 2018).

In order to avoid further financial burdens for beneficiaries and risk for providers, a clear rule—adopted with notice and opportunity for public comment from both beneficiaries and providers—is called for. To be sure, notice-and-comment was undertaken prior to the 2013 rule, but that rule did not resolve the issue of inpatient admissions. Further opportunity for comment by stakeholders and the public—informed by the experiences of providers and beneficiaries in recent years—would make for stronger

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80 Fed. Reg. 70,298, 70,305 (Nov. 13, 2015); Ctrs. for Medicare & Medicaid Servs., *Frequently Asked Questions: 2 Midnight Inpatient Admission Guidance & Patient Status Reviews for Admissions on or After October 1, 2013*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting_110413-v2-CLEAN.pdf (last visited Dec. 18, 2018).

regulatory policy. By engaging the public, HHS could benefit from the input of physicians and hospitals as to the pitfalls of the two-midnight rule and HHS's subsequent guidance, and obtain practical suggestions for a better course. Moreover, Medicare beneficiaries could bring their experiences to bear, so that the agency would have a better-informed approach going forward.

B. By Contrast, HHS's Use Of Notice-And-Comment Rulemaking Has Improved The Quality And Administrability Of Regulations.

On the other hand, where HHS has used formal, notice-and-comment rulemaking, public participation has led to better outcomes. Indeed, it can be no surprise that more information leads to better rulemaking. *See Sprint*, 315 F.3d at 373 ("[T]he notice requirement improves the quality of agency rulemaking by exposing regulations to diverse public comment.") (quoting *Small Refiner*, 705 F.2d at 547).

This is well exemplified by the important role the AMA plays in shaping Medicare reimbursement rules each year. Each summer, HHS publishes a proposed rule regarding the Medicare fee schedule for the following calendar year. *See, e.g., Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule*, 83 Fed. Reg. 35,704 (July 27, 2018). Among other things, the proposed rule revises payment policies and amounts for all physicians' services paid under the Medicare Physician Fee Schedule (PFS). *Id.* at 35,704-05. The goal of the proposed rule is to "ensure that . . . payment systems are updated to reflect changes in medical practice and the relative value of services." *Id.* at 35,705.

After publication, the AMA analyzes the proposed rule and solicits feedback from specialty and regional medical societies throughout the nation. *See, e.g.*, Andis Robeznieks, *Less Documentation, E/M Pay Changes Proposed in 2019 Fee Schedule*, Am. Med. Ass'n (Aug. 2, 2018), https://www.ama-assn.org/practice-management/medicare/less-documentation-em-pay-changes-proposed-2019-fee-schedule. Based on that feedback, the AMA submits a substantial set of comments, designed to identify unintended consequences, explain where pricing is inconsistent with physician experience, and also to laud positive policy changes. *See, e.g.*, Letter from James L. Madara, Am. Med. Ass'n, to Hon. Seema Verma, Administrator, Ctrs. for Medicare & Medicaid Servs. (Sept. 10, 2018), https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-9-10-2019-PFS-QPP-Comment-Letter-FINAL-2.pdf.

When drafting the final rule, HHS considers and incorporates the AMA's comments. *See, e.g.*, *Summary: 2019 Medicare Physician Fee Schedule and Quality Payment Program Final Rule* 2–3, Am. Med. Ass'n (2018), https://www.ama-assn.org/system/files/2018-11/pfs-qpp-final-rule-sum11-8.pdf (noting that CMS did not adopt certain aspects of the proposed rule that the AMA opposed). Sometimes, HHS even delays implementation of a proposed policy to give the AMA the opportunity to experiment or conduct further research and share its findings with the HHS. *See, e.g.*, *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule*, 83 Fed. Reg. 59,452, 59,638 (Nov. 23, 2018) (noting that a two-year delay in implementation for certain coding and payment related-changes would "provide the opportunity for

[CMS] to respond to the work done by the AMA" in that area).

This process permits efficient and centralized dialog between HHS, major stakeholders, and the public—and is accomplished within a matter of months. *See* Br. in Opp'n 35-36 & Addendum. Through this back and forth between the agency, the AMA, and in turn the regional and specialty groups, the final rules are better informed and more effective. Moreover, the public has a fulsome opportunity to weigh in on how Medicare's large and growing budget is directed. More rather than less formal rulemaking for Medicare is warranted.

CONCLUSION

Amici share respondents' concern with HHS's attempt to skip notice-and-comment rulemaking "when altering a substantive legal standard that reduces payments to hospitals—to the tune of billions of dollars." Br. for Resp'ts 2-3. In weighing HHS's stated concerns with inflexibility in its regulatory practices, the Court should also bear in mind the important benefits of generally applicable rules adopted through the notice-and-comment process.

Respectfully submitted,

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No. 17-1484

In the Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL., RESPONDENTS

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF OF *AMICI CURIAE* CATHOLIC HEALTH, ROCHESTER REGIONAL HEALTH, and SANFORD HEALTH IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether the Department of Health and Human Services was required to conduct notice-and-comment rulemaking before changing a substantive legal standard governing payment to hospitals under Medicare, a change that will cost hospitals as much as $4 billion for care they have already provided to low-income patients without private health insurance.

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INTEREST OF *AMICI CURIAE*[1]

Catholic Health is a non-profit healthcare system that provides care to Western New Yorkers across a network of hospitals, primary care centers, imaging centers, and other community ministries. The system includes Kenmore Mercy Hospital, Mercy Hospital of Buffalo, Mount St. Mary's Hospital, Sisters of Charity Hospital, and St. Joseph Campus.

Rochester Regional Health provides comprehensive care for Western New York and the Finger Lakes region through a broad spectrum of resources, an ability to advocate for better care, a commitment to innovation, and an abiding dedication to caring for the community. The system includes Rochester General Hospital, Unity Hospital, Newark-Wayne Community Hospital, Clifton Springs Hospital & Clinic, and United Memorial Medical Center.

Sanford Health is headquartered in the Dakotas and is the largest, rural, nonprofit health care system in the nation, with 45 hospitals and 289 clinics in nine states and five counties. With 28,000+ employees, including 1,300+ physicians in more than 80 specialty areas of medicine, Sanford Health is the largest employer in the Dakotas.

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that this brief was not authored in whole or in part by counsel for any party, and that no such counsel or party made a monetary contribution to fund the preparation or submission of the brief. A monetary contribution was made by McKay Consulting, Inc., an entity which is not a party to the case. In accordance with this Court's Rule 37.2, all counsel consented to the filing of the brief.

Amici have a strong interest in the outcome of this case, as they will suffer significant and direct financial loss if the government can change without notice the way that hospitals are reimbursed for services already provided to patients pursuant to the Medicare system. The government estimates that loss to be in the range of $3-$4 billion solely for the change at issue here. Pet. 14, 23.

Equally concerning to *Amici*, the Department's theory will justify similar changes to payment standards in the future, all without providing *Amici* or other hospitals the opportunity for the public notice and comment that Congress intended. *Amici* respectfully request that this Court affirm the well-reasoned decision of the D.C. Circuit.

STATUTORY PROVISIONS INVOLVED

42 U.S.C. § 1395hh(a)(2) states, in relevant part:

> No [1] rule, requirement, or other statement of policy . . . that [2] establishes or changes [3] a substantive legal standard [4] governing . . . the payment for services . . . shall take effect unless it is promulgated by the Secretary by regulation [through notice-and-comment rulemaking].

42 U.S.C. § 1395hh(a)(4) states:

> If the Secretary publishes a final regulation that includes a provision *that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule*, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation. [Emphasis added.]

INTRODUCTION

Every business in the country understands that the cost of goods and services it provides must have a close nexus to the amount of revenue the business expects to collect. Businesses that lack the ability to align costs and revenues go bankrupt.

The situation is no different for our nation's hospitals. This is particularly true when hospitals serve patients who depend on the government to pay the medical bills. Hospitals are happy to serve such patients. But the services they provide must be calibrated to the amount of revenue the hospitals can expect. Otherwise, hospitals, too, will go bankrupt.

Congress understood this reality when it enacted the notice-and-comment requirements that apply to Department of Health and Human Services changes in hospital reimbursement payment standards. Rather than incorporate the Administrative Procedures Act, Congress enacted two unique provisions. The first is 42 U.S.C. § 1395hh(a)(2), the "payment for services" provision. The second is 42 U.S.C. § 1395hh(a)(4), the "not a logical outgrowth" provision. In tandem, §§ (a)(2) and (a)(4) ensure that no hospital is stuck with the bill when the Department changes without advance notice how it reimburses hospitals.

Yet surprise is exactly what the Department sprung here. With the issuance of its 2012 Medicare "fractions" in 2014, the Department told hospitals that their reimbursements would be calculated at a lower rate. And the Department implemented this change with no notice or opportunity for hospitals to comment, contrary to §§ (a)(2) and (a)(4).

This change, if affirmed, will have a devastating impact on hospitals, especially those that have been most generous in serving low-income patients. In its petition, the government estimates the impact between $3 and $4 *billion* for fiscal years 2005 through 2013. Pet. 14, 23.

These amounts show why Congress dictated in § (a)(2) that the Department provide notice and an opportunity to comment when it alters standards governing the "payment for services" that hospitals receive. The requirement does not prohibit the Department from making changes; it merely prohibits the Department from pulling the rug out from under hospitals by unfairly changing the reimbursement payment standard without advance notice and an opportunity to comment.

Moreover, the burden on the Department is modest. The typical notice-and-comment period in this arena takes about 102 days. Br. in Opp'n App. 1a–3a. Yet those 15 weeks make all the difference in the world to hospitals. That is why the Department routinely provided notice and an opportunity to comment in more than a dozen previous attempts to revise the same payment standard at issue in this litigation. Br. in Opp'n App. 4a–6a.

As the D.C. Circuit concluded, § (a)(2)'s language is "fairly straightforward" (especially for Medicare) and its provisions are "readily met" here. Pet. App. 12a (Kavanaugh, J.). This Court should affirm the D.C. Circuit and hold the Department's 2012 reimbursement payment standard invalid.

STATEMENT

Medicare reimbursement in plain English

Medicare provides health insurance to elderly and disabled Americans. Pet. App. 2a. Patients can obtain insurance under different Medicare "Parts" specifying varying hospital-reimbursement methods. Pet. App. 2a–3a. What's important here is that monies paid to hospitals under Part A are adjusted when hospitals provide disproportionate services to low-income patients. Pet. App. 3a. This adjustment is based on the sum of two fractions. *Ibid.* The first fraction measures the percentage of Part A patients who are eligible for supplementary security income benefits. The second measures the percentage of all patients who were Medicaid-eligible but not Part A-eligible.

The dispute arises out of the Department's decision to change how it calculates the fractions used to determine a hospital's disproportionate share hospital reimbursement. As noted, the new standard will short the nation's hospitals between $3 and $4 billion. Pet. 14, 23. (Curiously, after relying in its petition on this massive change in the "payment for services" that hospitals receive, the Department's merits brief now suggests there might be no impact, Gov't Br. 4–5, highlighting the need for notice and public comment.)

Such a change in reimbursement dollars has a serious impact on an individual hospital's solvency and ability to provide future services. The question presented is whether the government was obligated to give hospitals advance notice and an opportunity to comment before the Department unilaterally implemented this change.

Medicare notice-and-comment requirements

Congress could have easily incorporated the APA when it established the notice-and-comment requirements for Department proposals to change Medicare reimbursement methods. It did not. Under the APA, only proposed "rules" require notice and an opportunity to comment. And even then, the APA excepts "interpretative rules, general statements of policy, [and] agency organization, procedure, [and] practice," plus circumstances where the regulating agency for "good cause" finds that notice and comment are "impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. § 553(b)(A), (B).

For Medicare, Congress broadened the types of covered agency actions to include not only "rules," but "requirements," and "statements of policy" as well. 42 U.S.C. § 1395hh(a)(2). So, whereas the APA *excludes* statements of policy from notice-and-comment procedures, § (a)(2) expressly *includes* them.

Congress then specified the subject matter to which § (a)(2) applies. Notice and comment are required when a rule, requirement, or statement of policy involves "the scope of benefits, the payment for services, or the eligibility . . . to furnish or receive services." *Ibid.*

As the D.C. Circuit explained, the above requirements constitute steps one and four of a four-factor inquiry under § (a)(2) for determining when notice and comment are necessary: (1) a rule/requirement/statement of policy that (2) "establishes or changes" (3) a "substantive legal standard" (4) governing the scope of benefits/ payment for services/eligibility. Pet. App. 12a.

In 2003, Congress created an extra layer of notice-and-comment protection for hospitals. This layer cannot be found in the APA. And it prohibits a Department regulatory provision from going into effect until after notice and adequate opportunity to comment. The requirement is triggered whenever a provision of the original (invalidated) final rule "is *not a logical outgrowth* of a previously published notice of proposed rulemaking or interim final rule." 42 U.S.C. § 1395hh(a)(4) (emphasis added).

A brief history of the Department's position on the disproportionate-services adjustment

The parties' dispute is over how the Department calculates the fractions used to calculate the disproportionate services adjustment. The nitty-gritty of the Department's thinking on the issue is of no moment. What does matter is the chronology for the Department's reimbursement payment standard:

- 2003 & before: hospital-friendly standard under the 1986 regulation
- 2003: the beginning of the faulty notice and comment; proposed rule clarifies that hospital-friendly standard does apply
- 2004: faulty notice and comment; final rule adopts Department-friendly standard
- 2007: with no notice or comment, amended regulation "confirms" 2004 final rule
- 2011: D.C. Circuit voids 2004 final rule's retroactive application

- 2013: after notice and comment, prospective new rule adopts Department-friendly payment standard

- 2014: D.C. Circuit vacates 2004 final rule altogether; not a "logical outgrowth" of the proposed rule

- 2014: 16 days after D.C. Circuit decision, Department issues fractions for 2012 adjustments, using Department-friendly rule and without notice and comment

- 2017: D.C. Circuit reverses Department's 2012 fractions because notice and comment was required

In its 2017 decision, the D.C. Circuit concluded that the Department's issuance of the adjustment fractions for 2012 violated both of Medicare's notice-and-comment provisions. The Department violated the "payment for services" standard in § (a)(2) because the new payment standard was (1) a "requirement" that (2) "changed" (3) a "substantive legal standard" (4) "used to calculate the payment that providers will receive." Pet. App. 12a–14a. And the Department violated the "not a logical outgrowth" standard in § (a)(4) because the Department's action in promulgating the new standard was "not a logical outgrowth of a previously published notice of proposed rulemaking." Pet. App. 17a–18a (citation omitted).

The D.C. Circuit denied the Department's request for rehearing en banc without a single member of the court calling for a vote. Pet. App. 77a–78a, 79a–80a. The Court then granted the Department's petition.

SUMMARY OF ARGUMENT

It is perverse for the government to tell hospitals that they will be reimbursed for services one way and then change the payment standard without formal notice. Congress so recognized when it enacted two separate statutes requiring the government to give notice and an opportunity for hospitals to comment before such changes are implemented. And while the Department is always free to change a reimbursement standard if it so chooses, the Department must give fair notice first. That never happened here when, in 2014, the Department started applying a Department-friendly payment standard with no notice or opportunity to comment. The D.C. Circuit was right to enforce Congress's intent and invalidate the Department's actions.

The Department advances a garbled reading of §§ (a)(2) and (a)(4). The Department urges the Court to allow the Government to skim some $3 to $4 billion that the Department would have been obligated to pay under the previous reimbursement payment standard. And that request necessarily requires the Court to greatly expand the Department's opportunity to make changes in payment-for-services standards in the future without first notifying hospitals of the modification. The Department's position flouts the plain, statutory language and any notion of fairness. This Court should summarily reject it.

ARGUMENT

It is undisputed that the Department did not use the notice-and-comment process to promulgate the revised reimbursement standard when it published the new fractions for 2012 in 2014. If §§ (a)(2) or (a)(4) required that process, then the Department's actions are void. Because the D.C. Circuit correctly concluded that notice and comment was required under both provisions, this Court should affirm.

I. The Government's application of its new, Department-friendly payment standard—without notice or comment—violates the payment-for-services provision in § (a)(2).

Once all the Medicare and administrative-law argle-bargle is cleared away, this case is not difficult. With an admitted $3 to $4 billion at stake, this is precisely the scenario Congress envisioned when it enacted § (a)(2) and directed the Department not to modify the payment standard for calculating payments for hospital services absent notice and comment.

Respondents' *prima facie* case for showing § (a)(2)'s applicability is straightforward, just as the D.C. Circuit concluded. First, the Department's new payment standard is, at the very least, a "requirement" or "statement of policy" guiding payment calculations. The Department does not contest the latter, Govt. Br. 39–41, even though Respondents raised it below, Resp't C.A. Br. 25; Resp't C.A. Reply 11, and again in this Court, Resp't Br. 27–29. And the Department's own description of its 2014 action shows it was, in fact, a "statement of policy." Resp't Br. 27–28.

Second, it is not possible to say that a payment-standard modification resulting in reimbursement checks that collectively shortchange hospitals somewhere between $3 to $4 billion is not a "change." The Government does not contest this point, nor could it.

Third and fourth, the standard for calculating a hospital's reimbursement is "a substantive legal standard governing . . . the payment for services." As the D.C. Circuit explained, "substantive law" is law that "creates, defines, and regulates the rights, duties, and powers of parties." Pet. App. 13a–14a (citing Black's Law Dictionary (10th Ed. 2014). When the Department revises a payment standard that determines a hospital's reimbursement amount, that revision "defines" the rights of parties.

The Department ignores this plain application of § (a)(2)'s language and urges this Court to import the APA's distinction between legislative and interpretative rules. Gov't Br. 21–29. But as noted above, Congress did not incorporate the APA by reference in § (a)(2); it rejected the APA's standards. For example, § (a)(2) requires notice-and-comment procedures for statements of policy, while the APA expressly excludes them. 5 U.S.C. § 553(b)(A). Section (a)(2) also requires notice-and-comment for "requirements," a term the APA does not even use. Section (a)(2) has a minimum 60-day minimum comment period, 42 U.S.C. § 1395hh(b)(1), whereas the APA's period is only a minimum of 30 days, 5 U.S.C. § 553(d). So, it is nonsensical to argue that the APA's standards have any force in the context of a § (a)(2) inquiry.

In addition, the phrase "substantive legal standard" is unique to § (a)(2). The APA does not use those words in combination, even one time. Instead, the APA refers to a "substantive rule." 5 U.S.C. § 553(d). So, this is not even a case where the Department is attempting to use words in one statute to discern the meaning of the same words in an unrelated statute, an analysis that is itself disfavored. *Chamber of Commerce* v. *Whiting*, 563 U.S. 582, 612 (2011) (Breyer, J., dissenting) (use of the same word in an unrelated statute does not "demonstrate what scope Congress intended the word" to have in the statute being scrutinized). The Department is using *different* words in an *unrelated* statute to discern the meaning of § (a)(2). That exercise is as illogical as it sounds.

The Department tries to argue that legislative history shows conclusively that § (a)(2) incorporates the APA's standards by silence. Gov't Br. 30—37. But "courts have no authority to enforce a principle gleaned solely from legislative history that has no statutory reference point." *Shannon* v. *U.S.*, 512 U.S. 573, 583 (1994) (cleaned up). "Congress's 'authoritative statement is the statutory text, not the legislative history.' " *Whiting*, 563 U.S. at 599 (quoting *Exxon Mobil Corp.* v. *Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005)).

There is no statutory reference point for the Department's position here. That the Department would spend eight precious pages of briefing to make an incorporation-by-legislative-history argument says everything this Court needs to know about the merits of the Department's textual arguments.

II. The Government's change to its Department-friendly payment standard—without notice or comment—violates the not-a-logical-outgrowth provision in § (a)(4) as well.

Independent of § (a)(2), § (a)(4) similarly requires notice and an opportunity to comment when the Department promulgates a regulatory provision that is not a "logical outgrowth" of the proposed regulation. 42 U.S.C. § 1395hh(a)(4). A provision may not become legally operative until going through the notice-and-comment process. *Id.*

Here, the D.C. Circuit vacated the Department's 2004 rule adopting the Department-friendly reimbursement standard because the 2004 rule "was not a logical outgrowth of the proposed rule," which was the hospital-friendly standard. *Allina Health Servs.* v. *Sebelius* (*Allina I*), 746 F.3d 1102, 1109 (D.C. Cir. 2014). To re-impose the voided rule, § (a)(4) required the Department to give the public notice and an opportunity to comment. But the Department did not do so with respect to its 2014 promulgation of the 2012 fractions based on the same, vacated payment standard.

The Department's response to this second notice-and-comment requirement is to say that it was acting by way of adjudication, rather than rulemaking. Gov't Br. 46–49. But adjudication is not an exception that appears in § (a)(4)'s text. And the Department's nationwide policy was not an adjudication in any event. Resp't Br. 51–52. Section (a)(4) required notice and comment before the Department could impose its new reimbursement payment standard.

CONCLUSION

The judgment of the D.C. Circuit Court of Appeals should be affirmed.

Respectfully submitted,

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No. 17-1484

IN THE

Supreme Court of the United States

ALEX M. AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

ALLINA HEALTH SERVICES, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF FOURTEEN STATE AND REGIONAL HOSPITAL ASSOCIATIONS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

The fourteen state and regional hospital associations described below respectfully submit this brief as *amici curiae*.

Amici's member hospitals and hospital systems are directly affected by changes to Medicare's "Disproportionate Share Hospital" program ("DSH"). Given their members' unique position on the front lines of low-income medical care, *amici* submit this brief to provide the Court with relevant information and guidance on two issues at the heart of this case: *first*, the purpose and importance of the DSH program to hospitals and low-income patients; and *second*, why notice-and-comment procedures are of particular significance in formulating rules that could have a material impact on the DSH program.

The Arkansas Hospital Association (ArHA) is a trade association representing over 100 hospitals and related institutions and the more than 41,000 individuals employed by these organizations across the state of Arkansas. The ArHA is committed to improving the health of Arkansans through the delivery of high quality, efficient, and accessible health care for all. Serving a diverse population in a predominantly rural state, 37 Arkansas hospitals depend on the DSH program to ensure that they can

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[1] Counsel for all parties have consented to the filing of this brief. In accordance with Rule 37.6, *amici* confirm that no party or counsel for any party authored this brief in whole or in part, and that no person other than *amici* or their counsel made any monetary contribution intended to fund the preparation or submission of this brief.

continue to provide and expand access to health care services to Arkansans, allowing them to receive the care they need close to home.

The California Hospital Association (CHA) is one of the largest hospital trade associations in the nation, serving more than 400 hospitals and health systems and 97 percent of the general acute care and acute psychiatric patient beds in California. CHA's members include all types of hospitals and health systems: non-profit; children's hospitals; those owned by various public entities; as well as investor-owned. CHA provides its members with state and federal representation in the legislative, judicial, and regulatory arenas in an effort to support and assist California hospitals in meeting their legal and fiduciary responsibilities; improve health care quality, access, and coverage; promote health care reform and integration of services; achieve adequate health care funding; improve and update laws and regulations impacting hospitals and health systems; and maintain the public trust in healthcare. As part of this, CHA often participates as an *amicus curiae* in appeals that have a substantial impact on hospitals and health systems. Two hundred forty-four (244) DSH hospitals are members of CHA.

The Georgia Hospital Association is a non-profit trade association made up of member hospitals and individuals in administrative and decision-making positions within those institutions. Founded in 1929, the Association serves 167 hospitals in Georgia. Ninety-two (92) of those hospitals receive DSH funding. The Association's purpose is to promote the health and welfare of the public through the

development of better hospital care for all of Georgia's citizens. The Association represents its members in legislative matters, as well as in filing *amicus curiae* briefs on matters of great gravity and importance to both the public and to health care providers serving Georgia citizens.

The Healthcare Association of New York State (HANYS) is New York's statewide hospital and health system association representing over 500 not-for-profit and public hospitals and hospital based skilled nursing facilities, home health agencies, and hospices. HANYS' members range from rural Critical Access Hospitals to large, urban Academic Medical Centers and other Medicaid and safety net providers. HANYS seeks to advance the health of individuals and communities by providing leadership, representation, and service to health providers and systems across the entire continuum of care. One hundred twenty-eight (128) of HANYS' members receive DSH funding.

The Greater New York Hospital Association (GNYHA) is a Section 501(c)(6) organization that represents the interests of approximately 140 Medicare providers located in New York, New Jersey, Connecticut, and Rhode Island, all of which are not-for-profit, charitable organizations or publicly-sponsored institutions. The vast majority of these hospitals and health systems receive DSH funding. GNYHA engages in advocacy, education, research, and extensive analysis of health care finance and reimbursement policy.

The Illinois Health and Hospital Association (IHA) is a statewide not-for-profit association with a membership of over 200 hospitals and nearly 50 health systems. For over 90 years, the IHA has served as a representative and advocate for its members, addressing the social, economic, political, and legal issues affecting the delivery of high-quality health care in Illinois. As the representative of virtually every hospital in the state, the IHA has a profound interest in this case. The IHA respectfully offers this *amicus curiae* brief in hopes of providing information not addressed by the litigants that will help the Court evaluate the litigants' arguments more thoroughly. One hundred thirteen (113) of IHA's member hospitals receive DSH funding.

The Massachusetts Health and Hospital Association (MassHA) is a voluntary, not-for-profit organization composed of hospitals and health systems, related providers, and other members with a common interest in promoting the good health of the people of the Commonwealth of Massachusetts. Through leadership in public advocacy, education, and information, MassHA represents and advocates for the collective interests of hospitals and health care providers, and it supports their efforts to provide high-quality, cost-effective, and accessible care.

Michigan Health & Hospital Association (MichHA) is the statewide leader representing all community hospitals in Michigan. Established in 1919, the MichHA represents the interests of its member hospitals and health systems in both the legislative and regulatory arenas on key issues and supports their efforts to provide quality, cost-

effective, and accessible care. Seventy-one (71) of MichHA's member hospitals receive DSH funding.

The New Jersey Hospital Association (NJHA) has served as New Jersey's premier health care association since its inception in 1918. NJHA currently has members across the health care continuum including hospitals, health systems, nursing homes, home health, hospice, and assisted living, all of which unite through NJHA to promote their common interests in providing quality, accessible, and affordable health care in New Jersey. In furtherance of this mission, NJHA undertakes research and health care policy development initiatives, fosters public understanding of health care issues, and implements pilot programs designed to improve clinical outcomes and enhance patient safety. NJHA regularly appears before all three branches of government to provide the judiciary and elected and appointed decision-makers with its expertise and viewpoint on issues and controversies involving hospitals and health systems. Fifty-two (52) of NJHA's member hospitals receive DSH funding.

The North Carolina Healthcare Association (NCHA) is a statewide trade association representing 136 hospitals and health systems in North Carolina, with the mission of uniting hospitals, health systems, and care providers for healthier communities. NCHA is an advocate before the legislative bodies, the courts, and administrative agencies on issues of interest to hospitals and health systems and the patients they serve. Eighty (80) of NCHA's member hospitals receive DSH funding.

The Ohio Hospital Association (OHA) is a private non-profit trade association established in 1915 as the first state-level hospital association in the United States. For decades, the OHA has provided a forum for hospitals to come together to pursue health care policy and quality improvement opportunities in the best interest of hospitals and their communities. The OHA is comprised of 237 hospitals and 13 health systems, all located in Ohio, and works with its member hospitals across the state to improve the quality, safety, and affordability of health care for all Ohioans. One hundred twelve (112) of OHA's member hospitals receive DSH funding. The OHA's mission is to collaborate with member hospitals and health systems to ensure a healthy Ohio.

The Hospital and Healthsystem Association of Pennsylvania (HAP) is a statewide membership services organization that advocates for nearly 240 Pennsylvania acute and specialty care, primary care, subacute care, long-term care, home health, and hospice providers, as well as the patients and communities they serve. One hundred two (102) of HAP's members receive DSH funding.

The Texas Hospital Association (THA) is a non-profit trade association representing Texas hospitals. THA advocates for legislative, regulatory, and judicial means to obtain accessible, cost-effective, high-quality health care. Two hundred five (205) of the THA's members receive DSH funding.

The Wisconsin Hospital Association (WHA) is a statewide non-profit association with a membership of more than 130 Wisconsin hospitals and health

systems. For nearly 100 years, the Wisconsin Hospital Association has advocated for the ability of its members to lead in the provision of high-quality, affordable, and accessible health care services, resulting in healthier Wisconsin communities. Wisconsin has 44 DSH hospitals.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

Amici's member hospitals and health systems serve diverse localities, including rural and urban communities all across the country. They employ millions of health care professionals. And they treat millions of low-income Americans. The services *amici*'s member hospitals provide to our nation's most vulnerable communities often go uncompensated, or are provided at deeply discounted rates. For these reasons, *amici's* members rely on programs established by federal and state governments to assist in providing care to low-income patients. In particular, many of *amici*'s member hospitals rely heavily on Medicare's "Disproportionate Share Hospital" program ("DSH"), which increases Medicare reimbursement rates for hospitals that serve a high-volume of low-income patients.[2]

The importance of the Medicare DSH program cannot be overstated to hospitals and their patients. Many hospitals that serve low-income communities are barely getting by—and indeed, hundreds have either closed in the past decade or are at risk of closing. Losses in government funding, including DSH funding, can force these hospitals to cut off services or close altogether. And when these hospitals close, it can have disastrous consequences, cutting off low-income Americans' access to emergency and primary care, eliminating much-

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[2] *See* 42 U.S.C. § 1395ww(d)(5)(F)(i)(I) (authorizing DSH adjustment payments).

needed jobs, and contributing to long-term health crises.

Because these hospitals rely on DSH funding, changes to the program, including to its adjustment formula, can have considerable impacts on their bottom line. As the D.C. Circuit has repeatedly observed, the rule at issue in this case itself may have an enormous financial impact on these institutions.[3] Yet, notwithstanding the importance of the program, the effect of changes to it are not always intuitive. For example, questions about whether a new adjustment formula (comprised of a complex set of variables that turn on data from other government programs) will result in greater or lower rates of reimbursement are not easy to answer. Likewise, understanding the consequences of a change on medical care *nationally* often requires careful analysis of the priorities, circumstances, and needs of thousands of *local* communities and hospitals.

The combination of these two factors—the clear importance of the DSH program, coupled with

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[3] *See Allina Health Servs. v. Price*, 863 F.3d 937, 939 (D.C. Cir. 2017) ("That difference in interpretation makes a huge difference in the real world. Part C enrollees tend to be wealthier than Part A enrollees. Including Part C days in Medicare fractions therefore tends to lead to lower reimbursement rates. Ultimately, hundreds of millions of dollars are at stake for the Government and the hospitals." (citing *Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 5 (D.C. Cir. 2011)). The Government initially acknowledged the impact of its rule change in its Petition for Writ of Certiorari. *See* Pet. at 23 ("HHS has informed this Office that the particular issue in this case concerning the proper interpretation of the Medicare-fraction statute alone implicates between $3 and $4 billion in reimbursement for FY2005 through FY2013.").

the uncertainty surrounding the impacts of changes to that program—underscores a key point that *amici* respectfully ask this Court to bear in mind as it considers this case: when it comes to the DSH program, notice-and-comment procedures are an essential component of rulemaking. Without notice-and-comment, the Department of Health and Human Services ("HHS") may fail to fully understand the range of consequences that a rule change will have on hospitals.

Put simply, notice-and-comment is vital to the successful administration of the DSH program. But one would be hard-pressed to understand why that is so from the Government's merits brief. As framed by the Government, the issue before this Court is "the scope of the notice-and-comment rulemaking requirements that the Department of Health and Human Services (HHS) must follow in administering the Medicare Act."[4] The Government barely addresses the DSH program at all, instead asserting that this Court's decision will determine whether HHS must use notice-and-comment in making *any and all* decisions relevant to a "panoply of Medicare contractor guidelines and manuals."[5] Having framed the question this way, the Government asserts that the policy implications of requiring notice-and-comment would be to jeopardize "the flexibility that is essential in light of Medicare's complex and

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[4] Petitioner's Brief ("PB") at 2.

[5] *Id.* at 21.

frequently changing statutory context and administrative developments."[6]

The Government is wrong, both in its framing and policy analysis. The question before this Court is nowhere near as broad as the Government describes it. It is, more narrowly, whether notice-and-comment was required under the *unique* circumstances of this case: where HHS made a material, substantive, and nationwide change in connection with how it treats Part C patients in calculating the disproportionate patient percentage—and, as Respondents further highlight, where HHS's choice to eschew notice-and-comment in making this change departed from past Agency practice reflecting HHS's own recognition of the importance of notice-and-comment in this context.[7] Contrary to the Government's suggestion,

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[6] PB at 42 (citing Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretative Rules*, 52 Admin. L. Rev. 547, 550-551 (2000)).

[7] *See* Respondents' Brief ("RB") at 10 ("To implement the DSH payment adjustment, including the determination of days in the DSH fractions, the agency has repeatedly used notice-and-comment rulemaking."). In their merits brief, Respondents further explain the relevance of the unique substantive contours of this rule, as well as the history of its promulgation, to understanding why the Government's policy argument and framing of the question presented are incorrect, and why the D.C. Circuit's holding will not encumber the ability of the Centers for Medicare & Medicaid Services to make non-material administrative changes in the context of the DSH program. *See id.* at 24 (summarizing the several reasons why "[t]he D.C. Circuit's holding will not impose the significant administrative burdens the Government suggests," and will have "virtually no implications outside this case."); *id.* at 54-59; *id.* at 55 ("The Government is also wrong to suggest that affirming the D.C. Circuit's Section 1395hh(a)(2) holding will have wide-ranging negative implications for the operation of Medicare.... Contrary to the Govern-

there are numerous reasons why notice-and-comment is critical *in this particular context*, especially where HHS's rule change may have a monumental effect on the financial viability of DSH hospitals that serve low-income patients. *Amici* thus respectfully submit this brief to provide the Court with important information about how the DSH program impacts its member hospitals and why notice-and-comment procedures are particularly important to material administrative decisions about DSH funding.

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ment's claim (Br. 42), the publication of binding fractions reflecting a renewed change in national Medicare DSH payment policy has no bearing on the agency's ordinary use of instructions and manual guidance to its contractors.").

ARGUMENT

I. CONGRESS CREATED THE DSH PROGRAM TO ASSIST HOSPITALS IN TREATING LOW-INCOME PATIENTS

A. Congress Created the Medicare DSH Program Both to Reimburse Hospitals for Caring for Low-income Patients, and to Ensure Such Hospitals Survive to Support Their Communities

In the early 1980s, Congress instituted reforms to the reimbursement process under Medicare.[8] In response, certain hospitals expressed concern that the rules—which lowered reimbursement rates—failed to consider the high costs associated with treating large numbers of low-income patients.[9] Responding to these concerns, Congress proposed cost adjustments for hospitals serving low-income communities, initially delegating the job of developing such adjustments to HHS.[10] When, after several years, HHS failed to act, Congress itself stepped in, establishing the DSH payment system in 1986 under the Comprehensive Omnibus Budget

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[8] *See* Lynne Fagnani and Jennifer Tolbert, *The Dependence of Safety Net Hospitals and Health Systems on the Medicare and Medicaid Disproportionate Share Hospital Payment Program*, National Association of Public Hospitals & Health Systems, at 3 (Nov. 1999), available at https://collections.nlm.nih.gov /catalog/ nlm:nlmuid-100927939-pdf.

[9] *See id.*

[10] *See id.*

Reconciliation Act (COBRA).[11] The program established criteria for "urban" and "rural" hospitals to qualify for DSH adjustment payments depending on their "disproportionate patient percentage"—a rough approximation for the proportion of care they provide to low-income patients.[12] In particular, it used the sum of two formulas to calculate this percentage: what the District Court in this case referred to as the "Medicare fraction" and the "Medicaid fraction."[13] The Medicare fraction takes the number of patient days for patients entitled to both Medicare Part A and supplemental security income benefits, and divides that number by the number of days for all patients entitled to benefits under Medicare Part A.[14] The Medicaid fraction, in turn, takes the number of patient days for individuals who are eligible for Medicaid but not entitled to benefits under Medicare Part A, and divides it by the total number of patient days.[15]

In creating the DSH program, Congress cited research suggesting two conclusions. *First*, it is more costly to treat low-income patients. Poorer patients

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[11] *See* 42 U.S.C. § 1395ww(d)(5)(F)(i); *see also* Disproportionate Share Hospital (DSH), CMS.gov, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html (last accessed Dec. 11, 2018).

[12] *See* 42 U.S.C. § 1395ww(d)(5)(F)(v); *see generally* 42 U.S.C. § 1395ww(d)(5)(F).

[13] *Allina Health Servs. v. Burwell*, 201 F. Supp. 3d 94, 98 (D.D.C. 2016); *see also Allina Health Servs. v. Price*, 863 F.3d 937, 939 (D.C. Cir. 2017).

[14] 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I).

[15] *See id.* at § 1395ww(d)(5)(F)(vi)(II).

seek medical care or intervention only for more severe problems, and thus tend to be sicker than comparable patients.[16] *Second*, hospitals that treat a large percentage of low-income patients tend to incur higher per-patient costs.[17] Given these realities, Congress expressed concern that if hospitals treating such patients did not receive additional financial assistance, they could close—which could have a stark effect on the low-income patients they served and on their communities.[18]

Under the DSH program, qualifying hospitals have received billions in federal funding to offset the costs of caring for low-income patients.[19] These payments, in turn, have been critical to hospitals that treat low-income and uninsured patients, and that,

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[16] *See* Felicien "Fish" Brown, *Health Policy – DSH Hospitals: Still Caring for the Poor*, Journal of the Catholic Health Association of the United States (Jan-Feb. 1999), available at https://www.chausa.org/publications/health-progress/article/january-february-1999/health-policy-dsh-hospitals-still-caring-for-the-poor (describing Congressional research that motivated the creation of DSH).

[17] *See Brown, supra* note 16.

[18] *See Brown, supra* note 16; *see also* Fagnani, note 8, at 5 ("[T]he purpose of the DSH program has evolved into the much broader one of protecting access to care for low-income patients by supporting the institutions that serve them.").

[19] *See* Fagnani, *supra* note 8, at 5. Medicaid has a separate DSH program, which—in concert with the Medicare DSH program—assists hospitals serving low-income patients through a federal/state partnership. *See Medicaid Disproportionate Share Hospital (DSH) Payments*, Medicaid.gov, https://www.medicaid.gov/medicaid/finance/dsh/index.html (last visited Dec. 11, 2018); Fagnani, *supra* note 8, at 7-11 (describing the history of this program).

without assistance, "have little capacity to recoup their costs ... by charging higher fees."[20]

B. DSH Payments Remain a Necessary Source of Funding for Hospitals Treating Low-income Patients

The DSH program has only grown in importance since it was first created, and it remains vital to assisting hospitals in providing uncompensated care to low-income and uninsured Americans. Such care is more important than ever in preventing long-term health crises, supporting low-income communities, and treating the millions of uninsured Americans who turn to safety net hospitals for services.[21]

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[20] Michael Spivey & Arthur L. Kellerman, *Rescuing the Safety Net*, 360 New Engl. J. Med. 2598, 2598 (June 18, 2009), available at https://www.nejm.org/doi/10.1056/NEJMp 0900728.

[21] *See* Fagnani, *supra* note 8, at v ("[t]he major sources of" reimbursement "safety net hospitals" receive for uncompensated care come from "Medicare and Medicaid [DSH] programs, along with appropriations from state and local governments"); Caitlin Podbielski, *Piling It on DSH Providers' Plate: Why PPACA's Eyes Are Bigger Than Its Stomach*, 20 Annals Health L. Advance Directive 144, 150–51 (2011) (describing "safety net hospitals" that require federal assistance to reimburse them for uncompensated care); Brown, *supra* note 16 (explaining "safety-net hospitals often treat a high percentage of Medicare and Medicaid patients," and that "Medicare DSH payments are an integral part of the[ir] overall revenue structure"); *id.* ("Catholic hospitals alone received $503 million in Medicare DSH payments last year."); Ariel Hart & Tamar Hallerman, *Grady, Georgia Hospitals Stand to Lose Millions in Federal Payments*, The Atlanta Journal-Constitution, Aug. 5, 2017, available at https://www.myajc.com/news/state-ampampamp-regional/grady-

To illustrate the continued significance of DSH funds, it is helpful to look at two particularly vulnerable categories of hospital (each of which is represented among *amici*'s membership): hospitals that treat low-income rural and urban communities.[22] Rural and urban hospitals are often dependent on DSH funds, and their closure or compelled curtailment of services would have disastrous effects on low-income Americans and their communities.

The rural health crisis is well-documented but often underappreciated. Rural hospitals that serve low-income communities are closing at an alarming rate.[23] These closures often result from a lack of

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georgia-hospitals-stand-lose-millions-federal-payments/cLZvuPw5flFUuehW1c292H/.

[22] Podbielski, *supra* note 21, at 146 (safety net hospitals "are typically located where the uninsured reside, in depressed rural communities and inner cities"); *accord* Spivey, *supra* note 20, at 2; Brown, *supra* note 16 ("Most DSH hospitals are in urban areas and often the only source of medical care for the poor, who are often uninsured. However, a significant number of these ... institutions exist in rural areas as well.").

[23] *See* Brittany Ruess, *Rural Hospitals on Life Support in Missouri*, Columbia Daily Tribune, Sept. 30, 2017, available at https://www.columbiatribune.com/news/20170930/rural-hospitals-on-life-support-in-missouri (describing a study by the National Rural Health Association that found "673 rural hospitals were at risk of closure and 210 [were] considered to be at an extreme risk for closing"); Jane Wishner, et al, *A Look at Rural Hospital Closures and Implications for Access to Care: Three Case Studies*, Kaiser Family Foundation (July 7, 2016), available at https://www.kff.org/report-section/a-look-at-rural-hospital-closures-and-implications-for-access-to-care-three-case-studies-issue-brief/ ("The number of rural hospital closures has increased significantly in recent years. This trend is expected to continue, raising questions about the impact the closures will have on rural communities' access to health care services."); Lisa

adequate funding to support low-income patients and a lack of reimbursement for uncompensated care.[24]

The effect of additional losses in funding for rural hospitals—and attendant closures——would be devastating. When rural hospitals close, low-income patients often have to drive long distances for health

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Rab, *Rural Hospitals Are Dying and Pregnant Women Are Paying the Price*, Politico (Oct. 3, 2017), https://www.politico.com/magazine/story/2017/10/03/meadows-medicaid-rural-hospitals-pregnant-women-dying-215671 (suggesting rural hospitals—to avoid closure—may close expensive units, such as maternity wards); Les Masterson, *Health Affairs: Ending Medicaid Expansion Would Cause Rural Hospitals to go Under*, HeathCareDive.com (Jan. 9, 2018), https://www.healthcaredive.com/news/health-affairs-ending-medicaid-expansion-would-cause-rural-hospitals-to-go/514307/; Michael Ollove, *'Safety Net' Hospitals Face Federal Budget Cuts*, Pew (Jan. 16, 2018), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/01/16/safety-net-hospitals-face-federal-budget-cuts (rural hospitals serving low-income communities "are struggling to keep their doors open"); Debby Warren, *Rural Hospitals Face Growing Financial Trouble, Says Moody's*, Nonprofit Quarterly (Sept. 11, 2018), https://nonprofitquarterly.org/2018/09/11/rural-hospitals-face-growing-financial-trouble-says-moodys/ (noting that the effect of closures could be the loss of 99,000 jobs, and the loss of direct access to care for nearly 12 million patients); Adrienne St. Clair, *Rethinking Rural Health Solutions to Save Patients and Communities*, NPR.org (Feb. 28, 2018), https://www.npr.org/sections/health-shots/2018/02/28/588826085/rethinking-rural-health-solutions-to-save-patients-and-communities.

[24] Wishner, *supra* note 23; Ruess, *supra* note 23 ("Uncompensated care, or care provided the hospital (sic) but not paid for, was largely to blame for the Fulton hospital's poor financial situation. This issue has become all too common for rural hospitals that are located in communities with higher rates of Medicare and Medicaid patients, poverty and people in worse health.").

care, and in the process can lose access to emergency care,[25] primary care,[26] and specialty care.[27] Further, the closure of such institutions can have unforeseen effects that go beyond the provision of medical care. The closure of a hospital can lead to job losses and make it harder for communities to attract new employers,[28] and can cut off other support services a

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[25] Wishner, et al, *supra* note 23 (noting that in case studies of rural hospital closures, "stakeholders emphasized that a major impact ... was the loss of access to emergency care in the community"); Rab, *supra* note 23 (noting that, for one patient, the closest hospital with a maternity ward was an hour away after her local hospital closed, and citing to studies that indicate that pregnant women who have to travel more than hour to give birth experience more negative medical outcomes); *Key Facts About the Uninsured Population*, Kaiser Family Foundation, at 8 (Dec. 07, 2018), https://www.kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/ ("[S]afety net providers have limited resources and service capacity, and not all uninsured people have geographic access to a safety net provider").

[26] Wishner, *supra* note 23 ("Because hospital emergency departments are a major source of primary care in rural areas, closures can have a significant impact on access to primary care, but some communities can fill these gaps."); Rab, *supra* note 23 (noting that pregnant women may miss prenatal appointments when long drives—the function of insufficiently close medical institutions—deter them from seeking care).

[27] Wisher, *supra* note 23 (noting that rural communities already faced shortages of specialty care, and that these "difficulties in accessing specialty care increased following the closures"); Health Policy Institute, *Rural and Urban Health, Data Profile Number 7*, Georgetown University (Jan. 2003), available at https://hpi.georgetown.edu/agingsociety/pubhtml/rural/rural.html (describing the physician shortage in rural America, including a severe shortage in mental health professionals).

[28] St. Clair, *supra* note 23 ("For many citizens in small-town America, losing the local hospital would threaten the livelihood

hospital provides to a community beyond direct care.[29]

To be sure, the financial picture for rural hospitals that treat low-income patients is complex. Medicare DSH adjustment payments are not the only source of funds keeping such vulnerable institutions afloat, and a lack of funding is not the only factor contributing to closures. But DSH funds are vital support that can be the difference between financial success and failure.[30] Indeed, the issue is not simply whether such vulnerable institutions will close. Instead, rural hospitals facing cuts in DSH funding face the impossible choices of which services to cut, and more starkly, whether they can continue at all to provide key services to low-income patients and communities—services that are typically unprofitable.[31]

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of the town and its people"); *accord* Wishner, et al., *supra* note 23; Rab, *supra* note 23.

[29] *See, e.g.*, Wishner, et al., *supra* note 23 (hospital staff had assisted the community by stabilizing individuals with acute mental health and addiction needs and arranging for their transport; when the hospital closed, "local capacity to address these needs disappeared").

[30] *See* Jack O'Brien, *After Individual Mandate Repeal, Who'll Pay for Rise in Uncompensated Care*, *Health*Leaders (Dec. 20, 2017), https://www.healthleadersmedia.com/finance/after-individual-mandate-repeal-who%E2%80%99ll-pay-rise-uncompensated-care (citing a study estimating that 35% of uncompensated care costs are covered by the federal government).

[31] *See* Podbielski, *supra* note 21, at 157-58; Robyn Whipple Diaz, *Unequal Access: The Crisis of Health Care Inequality for Low-Income African-American Residents of the District of Columbia*, 7 J. Health Care L. & Policy 120, 128–29 (2004).

Much like their rural counterparts, hospitals that treat low-income patients in urban communities are similarly dependent on DSH payments—and equally financially vulnerable.[32] In fact, cuts in DSH funding will arguably impact urban hospitals *more*, because those hospitals receive the bulk of Medicare DSH funding as an empirical matter.[33] What is more, closure of such facilities—or curtailment of services

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[32] *See* Diaz, *supra* note 31, at 121 (discussing the effect of the closure of D.C. General Hospital on the low-income African American community in Southeast D.C.); *see also* David Moyse, *Urban Legend: Dispelling the Myth That Rural Hospitals Require Increased Federal Funding at the Expense of Urban Hospitals*, 22 J. Contemp. Health L. & Policy 210, 217 (2005) ("The greater numbers of low-income, uninsured individuals living in urban areas strain hospitals because the individuals are unable to pay for rendered services"); *id.* at 210 (citing the "severe financial pressures and difficulties" faced by urban hospitals); Ollove, *supra* note 23 (noting that dramatic cuts in DSH funding could impair the New York City Health and Hospitals' ability to treat the 410,000 New Yorkers without health insurance); Debra A. Draper, et al., *Community Report: Financial Pressures Continue to Plague Hospitals*, Health System Change (Summer 2001), available at http://www.hschange.org/CONTENT/359/#jump1 ("Urban hospitals—which constitute the core safety net for low-income, uninsured individuals—have been particularly hard hit by declining patient volume and fewer privately insured patients."); Fagnani, *supra* note 8, at 5, 14, 19, 22 ("Medicare and Medicaid DSH payments have been a vital source of financing for these urban safety net hospitals;" "[w]ithout Medicare DSH payments, the hospitals [analyzed] would have experienced a 10 percent loss on Medicare payments;" and without DSH payments altogether, the "hospitals would have experienced an alarming negative 7 percent margin on total operations in 1996"); Brown, *supra* note 16 ("Medicare DSH payments are an integral part of the overall revenue structure of safety-net hospitals [in urban areas]").

[33] Fagnani, *supra* note 8, at 5.

they might otherwise offer—would have enormous consequences on low-income individuals' access to care.[34] And such closures can also have ripple effects, because urban hospitals often provide ancillary services, including disaster relief programs and even anti-terrorism response plans.[35]

Given the extraordinarily tight margins that DSH hospitals operate under, it should come as no surprise that the reimbursement process is crucial to their success or failure.[36] One study noted, for

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[34] Diaz, *supra* note 31, at 133 (describing difficulties faced by low-income D.C. residents in accessing primary care after the closure of D.C. General); *id.* at 121 ("Without access to these hospitals, many of D.C.'s poor African-American residents face[d] extremely limited access to health care services ...."); Renee Y. Hsia, et al. ***A US National Study of the Association Between Income and Ambulance Response Time in Cardiac Arrest,*** JAMA Network (Nov. 30, 2018), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2716993 (noting that "[i]n the wake of an increasing number of hospital and emergency department shutdowns, poorer neighborhoods and vulnerable populations have had even less access to care," which, in part, has contributed to an income gap in ambulance response time to a cardiac arrest).

[35] Spivey, *supra* note 20, at 2598 ("In many cities, large safety-net hospitals anchor their region's disaster-response plan. When such hospitals are forced to close or curtail key services, the spillover effects can reach far beyond the uninsured"); Moyse, *supra* note 32, at 219 (describing costly "anti-terrorism measures" implemented by urban hospitals after September 11, 2001).

[36] Fagnani, *supra note* 8, at 5 ("Hospitals that treat large numbers of low-income and uninsured patients often face severe financial difficulties as a result of their mission-related activities. Medicare DSH payments to these hospitals ease their financial burden and help to ensure their continued accessibility to the patients who use them."); Brown, *supra* note 16; Masterson, *su-*

example, that "[w]ithout sufficient DSH payments, the few hospitals that provide significant amounts of uncompensated care face financial crises, further endangering the ability of D.C.'s black poor to access health care services."[37] And as another expert succinctly explained: "even small changes in federal programs can have a disproportionate effect on the financial viability of these hospitals."[38] *Amici*'s members acutely experience those disproportionate effects, including and especially from the rule at issue in this case.

II. NOTICE-AND-COMMENT IS VITAL TO THE SUCCESS OF THE DSH PROGRAM

Given the DSH program's significance, it is especially important for stake-holders to have the opportunity to comment on proposed rules. Hospitals that treat low-income populations, in particular, can provide vital (and often little-known) information to HHS, especially in connection with changes to the DSH reimbursement formula. Allowing for this exchange of information, which is already the

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pra note 23 ("If Congress eliminated Medicaid expansion without increasing disproportionate share hospital (DSH) payments or other subsidies, more hospitals will close, especially in rural areas"); Craig B. Garner, *Medicare: The Perpetual Balance Between Performance and Preservation*, 30 J. Contemp. Health L. & Policy 279, 283 (2014) (detailing how reforms to Medicare and Medicaid policies have, historically, "raised the threat of catastrophic operating losses for hospitals unable to meet the demands to change"); Diaz, *supra* note 31, at 134.

[37] Diaz, *supra note* 31, at 134.

[38] Warren, *supra* note 23.

agency's regular practice,[39] will help HHS avoid material changes to the DSH program that could have drastic and unforeseen consequences.

The Government gives short shrift to the benefits of notice-and-comment procedures. Those benefits—conspicuously unmentioned in the Government's brief—have been well-articulated in the case-law[40] and the academic literature[41]—including by Professor Richard Pierce, whom the Government cites for the proposition that rule making can be cumbersome.[42]

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[39] RB at 58 ("[C]ontrary to the Government's suggestion, notice-and-comment rulemaking for Medicare payment standards, including for the DSH payment, is already the norm.").

[40] *See, e.g., Ass'n of Irritated Residents v. EPA*, 494 F.3d 1027, 1043 (D.C. Cir. 2007) ("The legislative history of the APA states that 'due to the unrepresentative nature of an administrative agency, "public participation ... in the rulemaking process is essential in order to permit administrative agencies to inform themselves and to afford safeguards to private interest."'" (quoting *Batterton v. Marshall*, 648 F.2d 694, 704 n.47 (D.C. Cir. 1980)); *Chocolate Mfrs. Ass'n of U.S. v. Block*, 755 F.2d 1098, 1103 (4th Cir. 1985) ("The notice-and-comment procedure encourages public participation in the administrative process and educates the agency, thereby helping to ensure informed agency decisionmaking.").

[41] *See* Jeffrey S. Lubbers, *A Guide to Federal Agency Rulemaking* 123 (5th Ed. 2012) ("[M]ost commentators have espoused the benefits of rulemaking over adjudication for policymaking.").

[42] PB at 42 (citing Pierce, *supra* note 6, 52 Admin. L. Rev. at 550-551); Richard J. Pierce, Jr., 1 *Administrative Law Treatise* 496 (5th Ed. 2010) ("Over the years, commentators, judges, and Justices have shown near unanimity in extolling the virtues of the rulemaking process over the process of making 'rules' through case-by-case adjudication."); *id.* at 496-501 (articulating

The Government quotes Professor Pierce in support of its argument that the "notice-and-comment process can be 'long and costly' and 'often requires many years and tens of thousands of person hours to complete.'"[43] But the Government fails to acknowledge Professor Pierce's immediately preceding discussion of the *benefits* of notice-and-comment procedures:

> The APA rulemaking procedure has many advantages. It enhances the quality of rules by allowing the agency to obtain a better understanding of a proposed rule's potential effects in various circumstances and by allowing the agency to consider alternative rules that might be more effective in furthering the agency's goals or that might have fewer unintended adverse effects. Second, it enhances fairness by providing all potentially affected members of the public an opportunity to participate in the process of shaping the rules that will govern their conduct or protect their interests. Finally, it enhances political accountability by providing the President and members of Congress a better opportunity to influence the rules that agencies issue.[44]

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nine benefits to rulemaking, including benefits flowing specifically from notice-and-comment).

[43] PB at 42.

[44] Pierce, *supra* note 6, 52 Admin. L. Rev. at 550.

If that were not enough, Professor Pierce's textbook on administrative law specifically draws an example from the Medicare context to illustrate the benefits of notice-and-comment procedures. According to Professor Pierce, a 1990s study detailing inconsistencies in reimbursement rates in Medicare provided "powerful new evidence" of the importance of formal rulemaking in Medicare decision-making.[45]

The general benefits of notice-and-comment rulemaking that Professor Pierce discussed apply with special force to the DSH program. *First*, as Professor Pierce observed, notice-and-comment provides an agency diverse perspectives from numerous stake-holders,[46] educates the agency about the relevant issue, "assure[s] responsive and responsible decisions,"[47] and thus leads to "informed administrative decisionmaking."[48] Indeed, because

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[45] *See Pierce, supra* note 42, *Administrative Law Treatise* at 501 (citing a GAO study indicating that a lack of rulemaking had resulted in major interregional inconsistences in reimbursement grant and denial rates as "powerful new evidence concerning the value of agency rules").

[46] Pierce, *supra* note 42, *Administrative Law Treatise* at 497; Att'y Gen.'s Comm. on Admin. Procedure, Administrative Procedure in Government Agencies, S. Doc. No. 77-8, at 101-02 (1st Sess. 1941) ("An agency's deliberations are not carried on in public and its members are not subject to direct political controls as are legislators ... [I]ts knowledge is rarely complete, and it must always learn the frequently clashing viewpoints of those whom its regulation will affect.").

[47] Glen O. Robinson & Ernest Gellhorn, *The Administrative Process* 809 (1974).

[48] *Ass'n of Irritated Residents*, 494 F.3d at 1043 ("[P]ublic participation assures that the agency will have before it the facts and information relevant to a particular administrative problem ...

notice-and-comment assists an agency in gathering information about a rule, many commentators, including Pierce, have cited its *efficiency* (notwithstanding the Government's suggestion that such rulemaking is inherently cumbersome).[49]

This kind of informed decision-making is especially valuable to the success of the DSH program. Hospitals treating low-income patients are not all the same. They face diverse problems, all of which can be relevant to the effect a change in DSH rules would have on their ability to serve low-income

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[and] increas[es] the likelihood of administrative responsiveness to the needs and concerns of those affected." (quoting *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1061 (D.C. Cir. 1987)); Lubbers, *supra* note 41, at 257; Pierce, *supra* note 6, 52 Admin. L. Rev. at 550 (Rulemaking "enhances the quality of rules by allowing the agency to obtain a better understanding of a proposed rule's potential effects in various circumstances and by allowing the agency to consider alternative rules that might be more effective in furthering the agency's goals or that might have fewer unintended adverse effects"); Eugene Scalia, *The Value of Public Participation in Rulemaking*, The Regulatory Review (Sept. 25, 2017), available at https://www.theregreview.org/2017/09/25/scalia-public-participation-rulemaking/ ("We value public participation in rulemakings in part because it is an opportunity to bring valuable evidence to the agency's attention, to explain effects of a proposed rule that the agency may not have appreciated, and simply to bring a perspective that the agency itself otherwise would not have.").

[49] Richard K. Berg, *Re-examining Policy Procedures: The Choice between Rulemaking and Adjudication*, 38 Admin. L. Rev. 149, 163 (1986) ("Such broader participation" through notice-and-comment "also makes rulemaking more efficient as an information-gathering technique for the agency"); Pierce, *supra* note 42, *Administrative Law Treatise* at 497.

patients.[50] It is impossible for HHS to predict the effect of a change on all of these stake-holders without consulting them. Hospitals, further, are better positioned to articulate the effect of a rule change on their ability to provide care.[51] They also will be able to identify far-reaching, but potentially unexpected, consequences to funding changes,[52] and provide up-to-date information about their industry that may illuminate the challenges they are facing and assist HHS in formulating a rule that better accomplishes the purpose of the program itself.[53]

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[50] *See, e.g.*, Moyse, *supra* note 32, at 212 (arguing HHS failed to consider unique needs of urban hospitals, and the financial impact upon them, in changing key rules); Diaz, *supra* note 31, at 133-34 (describing the specific needs of D.C. General—and the specific circumstances that made it unique from other hospitals, and contributed to its closure, including the fact that its uncompensated care costs were astronomical); Wishner, *supra* note 23 (analyzing three rural hospitals, and discussing with local thought leaders the particular reasons these hospitals were imperiled).

[51] *See, e.g.*, Ollove, *supra* note 23 (noting that funding cuts of less than a million dollars to a local Tennessee hospital (the largest employer in its community) could require cutting back on services, and possibly lead to the hospital's closure); *see id.* ("Other hospitals mentioned the possibility of cutting back on the number of social workers, follow-ups with patients after discharge, and transportation services to help poor patients get to medical appointments.").

[52] *See, e.g.*, Moyse, *supra*, note 32, at 218-19 (noting that hospitals have formulated emergency-response plans to respond to "biological or chemical weapon attacks"); *see also infra* notes 28-29, 35 and accompanying text (discussing potential impacts of hospital closures on communities beyond access to health care).

[53] Draper, *supra* note 32 (explaining how changes in health plans' inpatient utilization management efforts have affected hospital revenues); Fagnani, *supra* note 8, at vi (noting that

Second, as Professor Pierce stated, notice-and-comment allows "all potentially affected members of the public an opportunity to participate in the process of shaping the rules that will govern their conduct and protect their interests."[54]

This principle is again particularly important in the DSH context. Hospitals across the country face enormous challenges, and their ability to stay open in the face of a shifting health care landscape and funding cuts often turns on the herculean efforts of care-givers.[55] These hospitals face pressures to cut back on the very services the DSH program is

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DSH changes would be particularly problematic in light of "local government appropriations," "market forces," and an "eroding Medicaid patient base"); *id.* (explaining that new technologies have made medical care more outpatient-focused, rather than in-patient focused, and criticizing the DSH qualifying formula for failing to consider this industry trend); Brown, *supra* note 16 (explaining how changes to commercial insurers' reimbursement rates will make Medicare DSH payments all the more significant—and that without those payments, market forces will push hospitals to "reduce their commitment to serving the poor"); *see also* Lubbers, *supra* note 41, at 271-72 ("[T]here is little question that agencies must and do take comments seriously and often modify the final rule as a result of them").

[54] Pierce, *supra* note 6, 52 Admin. L. Rev. at 550; Lubbers, *supra* note 41, at 123 ("A rule formulated after rulemaking ... is fairer to the class of persons who would be affected by [it] than a rule announced in an adjudication" (internal quotation marks omitted)); Robinson and Gellhorn, *supra* note 47, at 809 (notice-and-comment "can serve as a safety valve allowing interested persons and groups to express their views before policies are announced and implemented").

[55] *See, e.g.*, Ollove, *supra* note 23 (interviewing the CEO of a local Tennessee hospital, who detailed his efforts to keep the hospital afloat in the face of budget cuts).

designed to help them provide: unprofitable services to low-income Americans.[56] Including these hospitals in the process of creating the rules that govern their ability to provide that care is not just important to ensuring the best rules are adopted. It is also critical to ensuring such hospitals are treated as partners in the program's overarching mission.

What is more, DSH hospitals can more effectively serve as the voices for the patients they serve, who are most directly impacted by material changes in DSH funding. Those low-income patients, however, are likely to be unfamiliar with the administrative process and therefore unable to share their perspectives on these vital issues. Notice-and-comment can ensure the hospitals, and their patients who are directly affected by the policy and changes to it, have a say in the administrative rule-making process.

If the importance of notice-and-comment to the DSH program is not already clear, this case illustrates it in spades. The Government's merits brief, for example, noticeably elides the question whether its new rule would *in fact* result in greater or lower reimbursement rates. The Government explains that "[i]f, as the court of appeals assumed,

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[56] *See, e.g.*, Diaz, *supra* note 31, at 128-29 ("Provision of services to those without adequate medical insurance is unattractive to health care providers, and may cause hospitals and individual physicians to terminate or severely limit services to the uninsured."); Podbielski, *supra* note 21, at 147 ("Tax-exempt hospitals, specifically, have historically offered some of these services to eligible individuals free of charge as charity care, but in an era of negative operating budgets, charity care has become a controversial and arguably waning practice.").

'Part C enrollees [are] wealthier than Part A enrollees,' the inclusion of Part C Patients in the Medicare fraction would—if the assumption is true—tend to reduce the value of the fraction (and thus possibly reduce the amount of respondents' 'additional payment.')"[57] The Government then attempts to undercut this assumption—casting doubt through citation to "research" that has "shown that Part C enrollees tend to have lower incomes at similar rates as Medicare beneficiaries who are not enrolled in Part C."[58] The purpose of the sentences may be to suggest to this Court that the Government's rule change is not particularly significant—a position the Government itself has previously contradicted.[59] But HHS's own lack of clarity about the impact of its rule is telling in a different way. The question before this Court is *not* whether the rule change, in fact, will dramatically lower the adjustment rates for hospitals serving low-income patients, as the D.C. Circuit suggested it would.[60] Instead, the question is what process should

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[57] PB at 4 (citation omitted).

[58] *Id.* at 4-5

[59] In contrast to its merits brief, which implies to the Court that the rule change at issue here would *not* have a major financial impact on hospitals, the Government previously represented to this Court that the rule *would* have a major financial impact—in seeking review. Pet. at 23 ("HHS has informed this Office that the particular issue in this case concerning the proper interpretation of the Medicare-fraction statute alone implicates between $3 and $4 billion in reimbursement for FY2005 through FY2013.").

[60] *Allina Health Servs.*, 863 F.3d at 939. The question of how much this very rule will cost was also the key issue when HHS previously attempted to promulgate this same rule in 2004. The Agency first proposed to interpret the DSH formula consistent

be employed to ensure that the Agency, in making a new rule, knows the answer to significant questions and has worked with diverse stake-holders to understand the consequences of its rule.[61]

Put another way, notice-and-comment does not promise an outcome. But it does provide a process for ensuring that the government receives relevant information before making consequential administrative decisions. That process is especially important where, as here, modest changes to the

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with its past practice, and not consider patients enrolled in Medicare Part C as part of the Medicare fraction. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1106 (D.C. Cir. 2014); *see also* RB at 11-15 (detailing the history of the notice, adoption, and challenges to the 2004 rule). In doing so, it indicated that the rule would have no major "financial impact," and received only 26 comments. *See id.* It then adopted the opposite interpretation—which resulted in tens of millions of dollars less in adjustment payments per year. *Allina*, 746 F.3d at 1107. The Agency's failure to announce the *actual* rule change it was contemplating failed, in turn, to generate the very comments which would have flagged this enormous financial impact—and likely challenged the rule. And, indeed, the D.C. Circuit held that the rule ultimately promulgated was not a logical outgrowth of the rule announced *precisely* because of the enormous distinction in cost. *See Allina*, 746 F.3d at 1109. In short, the Agency has long waffled on the precise cost of this rule—and long avoided properly using a notice-and-comment procedure that could have provided a meaningful forum to actually address this cost and its impact. *See generally* RB at 11-15.

[61] *See* Pierce, *supra* note 42, *Administrative Law Treatise* at 499 (Through notice–and-comment "valuable comments will go far beyond lawyers' arguments" and "will include studies and affidavits of experts in a variety of fields supporting the agency's views, contradicting its views, criticizing the agency's studies, and proposing more effective or less intrusive alternatives to the agency's proposal").

DSH program will have outsized effects on our most vulnerable citizens, and where, as here, input from stake-holders can fill glaring gaps in agency knowledge.

CONCLUSION

The Medicare DSH program is a vital lifeline for hospitals serving low-income, vulnerable communities. Changes to that program can have enormous and unexpected effects on these hospitals. Notice-and-comment procedures can ensure that those changes are implemented after agency consultation with diverse stake-holders, which can help prevent mistakes that could have dramatic and irreversible consequences on the patients and communities these hospitals serve. *Amici* respectfully submit that the Court should be mindful of these consequences, this DSH context, and the benefits of notice-and-comment as it evaluates the legal issues in this case.

Respectfully submitted,

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In the
Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

ALLINA HEALTH SERVICES, et al.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF FOR *AMICI CURIAE* 77 HOSPITALS AND SOUTHWEST CONSULTING ASSOCIATES IN SUPPORT OF RESPONDENTS

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STATEMENT OF INTEREST[1]

Amici are 77 hospitals across the country and Southwest Consulting Associates, a financial consulting group that provides healthcare finance and compliance consulting services to healthcare providers. *Amici* hospitals span urban, suburban, and rural areas across 22 different states and range in size from 20 beds to 1,343 beds. As is common among hospitals, *amici* devote a substantial and disproportionate share of their resources to treating low-income patients, which makes the adjustment Congress provided to Medicare reimbursements for hospitals that do so of critical importance to their continued ability to serve those most in need. *Amici* thus can attest to the substantial impact that (even ostensibly minor) regulatory adjustments have on their Medicare reimbursements and in their internal budgeting, financial forecasting, and management. To take the issue underlying this case as an example, depending on the size of the hospital and a variety of other factors, the impact for any given individual *amicus* hospital of including Part C days in the Medicare fraction ranges anywhere from less than $100,000 to more than $27 million.

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae*, their members, their consultants, and their counsel, made any monetary contribution toward the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.3, counsel of record for all parties have consented to this filing in letters on file with the Clerk's office.

Because Medicare payment rates and adjustments are so critical to their continued ability to provide care on the front lines, *amici* have, of necessity, become every bit as well versed in the complex regulatory scheme of Medicare and Medicaid as the Secretary and his agencies. As such, *amici* are uniquely well positioned to speak to the importance of agency accountability, predictability, and stability in this context, and to explain how traditional notice-and-comment rulemaking has long served those interests.

A full list of *amici* is set forth in the appendix to this brief.

SUMMARY OF ARGUMENT

Notice-and-comment rulemaking is essential to the effective operation of the modern Medicare system. In 1983, Congress shifted the Medicare system from one in which hospitals were reimbursed after the fact based on the actual costs of serving Medicare patients, to one in which standard reimbursement rates are fixed in advance based on specified categories of patient diagnoses, and a hospital is reimbursed based on those rates regardless of the actual costs of its services. The shift to a prospective payment system reflected an effort to incentivize hospitals to be more efficient and cost-effective in the provision of services. But the success of that effort depends on hospitals actually knowing *in advance* what those fixed payment rates will be, as well as how the myriad adjustments that the Medicare Act establishes to their payments will be calculated. To that end, Congress coupled the shift to a prospective payment system with a specific

requirement that the Secretary of Health and Human Services ("Secretary") must employ notice-and-comment rulemaking for every "rule, requirement, or other statement of policy ... that establishes or changes a substantive legal standard governing ... the payment for services." 42 U.S.C. §1395hh(a)(2).

Consistent with that and other rulemaking obligations, the Secretary undertakes a comprehensive rulemaking each year, published in the Federal Register under the title "Proposed Rules" or "Rules and Regulations," to explain what the rates will be and how adjustments to hospitals' payments will be calculated in the following fiscal year. And the Secretary has long used that mandatory annual notice-and-comment rulemaking process to propose and promulgate changes to how the disproportionate share hospital ("DSH") adjustment—*i.e.*, the adjustment for hospitals that devote a disproportionate share of their resources to treating low-income patients—will be calculated in the coming year. Indeed, the Secretary employed notice-and-comment rulemaking when the agency first tried to adopt the payment policy underlying this case, and has addressed the calculation of the DSH adjustment in all but four of the 33 rounds of annual proposed and final rulemakings since 1986. The Secretary deviated from that practice in the fiscal year presently at issue only because his effort to alter how the DSH calculation was adjusted through notice-and-comment rulemaking was *rejected*, on account of a failure to provide the notice necessary to allow for meaningful comment.

This case thus is manifestly not about an effort to saddle the Secretary with some onerous new notice-and-comment rulemaking requirement. It is simply about whether the Secretary must continue to use notice and comment in a context in which he has long done so—namely, when changing the substantive standards governing the calculation of prospective payment rates and adjustments. Relieving the Secretary of that obligation not only would be contrary to the plain text and intent of Congress, but would deprive hospitals and the rest of the regulated community of the fair notice and accountability on which the prospective payment system depends.

After all, even seemingly small changes can have enormous financial implications in this context, and those implications are particularly acute for the precise hospitals that the DSH adjustment is designed to assist—*i.e.*, those that spend a disproportionate share of their resources caring for low-income individuals. Notice and comment thus not only ensures that the Secretary will not *inadvertently* make seemingly minor changes with drastic consequences for hospitals, but also gives courts the tools to hold the Secretary accountable when (as here) he tries to deviate from settled practice *sub silentio*, and without regard for the true economic impact that those actions will have on the ability of hospitals to continue serving those most in need. Accordingly, the Court should decline the Secretary's invitation to disrupt the status quo, and instead ensure that the regulated community continues to receive the fair notice, transparency, and accountability that the Medicare Act's notice-and-comment rulemaking requirements command.

ARGUMENT

I. Robust Notice-And-Comment Rulemaking Is Critical To The Effective Operation Of The Medicare Act's Prospective Payment System.

A. Notice-and-Comment Rulemaking Has Long Been a Fixture of the PPS System.

Medicare is a federal health insurance program for the elderly and disabled. *See* 42 U.S.C. §1395 *et seq.* At its inception, Medicare reimbursed hospitals retrospectively on the basis of their "reasonable costs" of treating Medicare patients. But in 1983, Congress shifted to a prospective payment system ("PPS") under which, rather than compensating hospitals retrospectively based on their actual costs, the Secretary prospectively fixes standard reimbursement rates, and a hospital receives those rates regardless of how much its treatments actually cost. *See Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994). Congress designed this prospective, fixed reimbursement system to incentivize hospitals to provide more cost-effective care. By giving hospitals advance notice of what reimbursement they will receive, the PPS system allows hospitals to use that information when planning and budgeting for the coming year.

"Indeed, this link between prospectivity and efficiency lay at the heart of Congress' purpose when it created the PPS system[.]" *Id.* As the accompanying House Report explained, the shift to a prospective system was "intended to reform the financial incentives hospitals face, promoting efficiency in the provision of services by rewarding cost/effective

hospital practices." H.R. Rep. No. 98-25, at 132 (1983), *reprinted in* 1983 U.S.C.C.A.N. 219, 351; *see also* S. Rep. No. 98-23, at 47 (1983), *reprinted in* 1983 U.S.C.C.A.N. 143, 188 (prospective system was "intended to create incentives for hospitals to operate in a more efficient manner, since hospitals would be allowed to keep payment amounts in excess of their costs and would be required to absorb any costs in excess of the [fixed] rates"). Over the decades since 1983, the prospective payment approach has been extended far beyond acute inpatient hospitals, to home health agencies, hospice, hospital outpatient, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and skilled nursing facilities. *See Prospective Payment Systems - General Information*, CMS, https://go.cms.gov/2uIwOE9 (last visited Dec. 20, 2018).

It is thus no surprise that Congress has deemed notice-and-comment rulemaking particularly critical to the effective operation of the Medicare Act. After all, a *prospective* system designed to incentivize efficiency and cost-effective practices cannot achieve those ends if hospitals do not have advance notice of the rates Medicare will pay and how adjustments to those rates will be calculated. *See Methodist Hosp.*, 38 F.3d at 1227 ("Congress designed this system to encourage health care providers to improve efficiency and reduce operating costs."). In keeping with that commonsense point, Congress coupled the shift to a PPS system with an obligation that the Secretary must "provide for publication in the Federal Register, on or before the August 1 before each fiscal year ..., a description of the methodology and data used in

computing the adjusted [diagnosis-related group ("DRG")] prospective payment rates under this subsection, including any adjustments required under subsection (e)(1)(B)." 42 U.S.C. §1395ww(d)(6).

And Congress did not stop there. Concerned that "important policies [were still] being developed without benefit of the public notice and comment period," H.R. Rep. No. 100-391(I), at 430 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-250, Congress imposed additional notice-and-comment rulemaking requirements in 1987, including the requirements at issue here. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, §4035, 101 Stat. 1330, 1330-78. Those amendments made clear that the Secretary must use notice-and-comment rulemaking not only to explain how PPS rates and certain adjustments specified in 42 U.S.C. §1395ww(d)(6) would be calculated, but for *every* "rule, requirement, or other statement of policy ... that establishes or changes a substantive legal standard governing ... the payment for services." 42 U.S.C. §1395hh(a)(2). After all, only if hospitals *actually* "receive advance notice" of how Medicare will reimburse them can they attempt to "improve efficiency and reduce operating costs" based on the prospectively fixed rates and reimbursement methodologies in that notice. *Methodist Hosp.*, 38 F.3d at 1227.

Consistent with those obligations, each year the Secretary undertakes a comprehensive notice-and-comment rulemaking that sets forth on a prospective basis not only the rates that providers can receive for their services in the coming year, but also how the

Medicare Act's myriad adjustments to those rates will be calculated. That annual rulemaking, which typically takes between three and four months, *see* BIO.Add.1a-3a, addresses all manner of issues related to the methodology through which payments and adjustments are calculated.

For example, "in May 2007, [the Secretary] published a proposed rule for fiscal year 2008 that would offset the rural floor by adjusting area wage indexes rather than by adjusting the standardized amount as CMS had done in the past." *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 208 (D.C. Cir. 2011) (citing 72 Fed. Reg. 24,680 (May 3, 2007)); *see also* 72 Fed. Reg. 47,130 (Aug. 22, 2007). The Secretary also has undertaken lengthy notice-and-comment rulemaking efforts with regard to cancer hospitals and potential adjustments for the specialized services they provide, *see H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 7-9 (D.D.C. 2018) (summarizing rulemaking beginning in 2010), *appeal filed*, No. 18-6277 (D.C. Cir. Sept. 19, 2018), as well as decades-long efforts regarding the grouping of hospitals into geographic areas, *see Bellevue Hosp. Ctr. v. Leavitt*, 443 F.3d 163, 169-72 (2d Cir. 2006) (summarizing rulemaking beginning in 1985). And the Secretary has routinely employed notice-and-comment rulemaking to adjust how "inpatient" and "outpatient" services are defined, an issue that has a substantial effect on payments. *See Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 243 (D.D.C. 2015) (citing 78 Fed. Reg. 50,496, 50,965 (Aug. 19, 2013)); *see also* 77 Fed. Reg. 45,061, 45,155 (July 30, 2012); 77 Fed. Reg. 68,210, 68,430-31 (Nov.

15, 2012); 78 Fed. Reg. 27,486, 27,644-50 (May 10, 2013).

The Secretary also has a long and robust history of using notice-and comment in the specific context relevant here—*i.e.*, the DSH adjustment. Indeed, even before Congress codified the DSH adjustment formula, the Secretary used notice and comment to discuss a potential "adjustment ... for hospitals that serve a disproportionate share of low income or Medicare patients or both and that a definition of these hospitals be established based on a broader concept of low income than simply percentage of Medicaid patients." 50 Fed. Reg. 35,646, 35,685 (Sept. 3, 1985); *see also id.* at 35,686. And after Congress codified the DSH adjustment formula in 1986, the Secretary routinely used the annual notice-and-comment rulemaking process to address how the DSH adjustment would be calculated. *See, e.g.*, 51 Fed. Reg. 16,772, 16,776-78 (May 6, 1986); 51 Fed. Reg. 31,454, 31,457-61 (Sept. 3, 1986); 53 Fed. Reg. 38,476, 38,480-81, 38,516 (Sept. 30, 1988); 54 Fed. Reg. 36,452, 36,489 (Sept. 1, 1989); 55 Fed. Reg. 35,990, 35,992-94 (Sept. 4, 1990); 56 Fed. Reg. 568, 571 (Jan. 7, 1991); 56 Fed. Reg. 43,196 (Aug. 30, 1991); 58 Fed. Reg. 46,270, 46,313 (Sept. 1, 1993); 59 Fed. Reg. 45,330, 45,374 (Sept. 1, 1994); 60 Fed. Reg. 45,778, 45,811-12 (Sept. 1, 1995).

In addition to providing the regulated community with advance notice of potential changes to how the DSH adjustment would be calculated, notice and comment has promoted valuable dialogue between the Secretary and the regulated community. For example, in the proposed rulemaking for fiscal year ("FY") 1997,

the Secretary sought comments and feedback on alternatives to various aspects of the methods and data used to calculate the DSH fractions and adjustment. *See* 61 Fed. Reg. 27,444, 27,473-74 (May 31, 1996). The Secretary did not enact any changes to the calculation methods in the final rule released later that year, but the Secretary did note that the request for comments had been fruitful in providing feedback on how "to improve the data and the calculation to better target those hospitals that treat a disproportionate share of the indigent population." 61 Fed. Reg. 46,166, 46,206-07 (Aug. 30, 1996).

The Secretary thereafter addressed the DSH adjustment in every single one of the annual proposed and final rulemakings for the next six fiscal years. *See* 62 Fed. Reg. 29,902, 29,933 (June 2, 1997); 62 Fed. Reg. 45,966, 46,001-02 (Aug. 29, 1997); 63 Fed. Reg. 25,576, 25,594-95 (May 8, 1998); 63 Fed. Reg. 40,954, 40,984-85 (July 31, 1998); 64 Fed. Reg. 24,716, 24,745-46 (May 7, 1999); 64 Fed. Reg. 41,490, 41,539 (July 30, 1999); 65 Fed. Reg. 26,282, 26,307-08 (May 5, 2000); 65 Fed. Reg. 47,054, 47,086-87 (Aug. 1, 2000); 66 Fed. Reg. 22,646, 22,690 (May 4, 2001); 66 Fed. Reg. 39,828, 39,882-83 (Aug. 1, 2001); 67 Fed. Reg. 31,404, 31,462-63 (May 9, 2002); 67 Fed. Reg. 49,982, 50,060-61 (Aug. 1, 2002). And the Secretary proceeded to address the precise issue underlying this case (Part C days) in each of the four subsequent proposed and final rules, proposing to "clarify" its policy on that issue in the proposed rulemaking for FY 2004, deferring action on that issue in the final FY 2004 rulemaking, further deferring action in the proposed rulemaking for FY 2005, then attempting to adopt the

position it now presses in the final FY 2005 Rule. *See infra* Part II.B.

Since then, the Secretary has continued to address DSH-related issues in its annual notice-and-comment rulemaking routinely. *See, e.g.*, 70 Fed. Reg. 23,306, 23,434-36 (May 4, 2005); 70 Fed. Reg. 47,278, 47,438-43 (Aug. 12, 2005); 71 Fed. Reg. 23,996, 24,107-08 (Apr. 25, 2006); 71 Fed. Reg. 47,870, 48,066-67 (Aug. 18, 2006); 74 Fed. Reg. 24,080, 24,187-91 (May 22, 2009); 74 Fed. Reg. 43,754, 43,899-908 (Aug. 27, 2009); 75 Fed. Reg. 23,852, 24,002-07 (May 4, 2010); 75 Fed. Reg. 50,042, 50,275-86 (Aug. 16, 2010); 76 Fed. Reg. 25,788, 25,942-44 (May 5, 2011); 76 Fed. Reg. 51,476, 51,681-83 (Aug. 18, 2011); 77 Fed. Reg. 27,870, 27,974-75 (May 11, 2012); 77 Fed. Reg. 53,258, 53,411-13 (Aug. 31, 2012).

Indeed, the Secretary used notice-and-comment rulemaking when the Secretary once again altered the treatment of Part C days in 2013. *See* infra Part II.B; 78 Fed. Reg. 27,486, 27,577-78 (May 10, 2013); 78 Fed. Reg. 50,496, 50,613-47 (Aug. 19, 2013); 78 Fed. Reg. 61,191, 61,191-97 (Oct. 3, 2013). And the Secretary has continued to address DSH-related issues in subsequent rulemakings as well. *See, e.g.*, 79 Fed. Reg. 27,978, 28,094-104 (May 15, 2014); 79 Fed. Reg. 49,854, 50,004-22 (Aug. 22, 2014); 80 Fed. Reg. 24,324, 24,480-88 (Apr. 30, 2015); 80 Fed. Reg. 49,326, 49,512-30 (Aug. 17, 2015); 81 Fed. Reg. 24,946, 25,081-94 (Apr. 27, 2016); 81 Fed. Reg. 56,762, 56,943-73 (Aug. 22, 2016); 82 Fed. Reg. 19,796, 19,940-55 (Apr. 28, 2017); 82 Fed. Reg. 37,990, 38,189-220 (Aug. 14, 2017); 83 Fed. Reg. 20,164, 20,386-401, 20,547-48 (May 7,

2018); 83 Fed. Reg. 41,144, 41,401-28, 41,682-84 (Aug. 17, 2018).

As the foregoing makes clear, affirming the D.C. Circuit's conclusion that a change to how the DSH adjustment will be calculated constitutes a "rule, requirement, or other statement of policy ... that establishes or changes a substantive legal standard governing ... the payment for services," 42 U.S.C. §1395hh(a)(2), would not "substantially undermine the agency's ability to administer the Medicare program," let alone "cripple effective administration of the Medicare program," Pet'r.Br.18. Not only is the Secretary fully capable of addressing changes to the DSH adjustment through notice-and-comment rulemaking; that is what the Secretary has been doing for decades. The Secretary deviated from that approach in June 2014—when HHS published the Medicare fractions to be used in calculating DSH adjustments for FY 2012, Pet.App.5a-6a—only because the Secretary's first effort to effectuate the policy change through notice-and-comment rulemaking *failed*, on account of the agency's failure to provide the notice necessary to allow the regulated community to comment on that proposed change. *See infra* Part II.B; *Allina Health Servs. v. Sebelius* (*Allina I*), 746 F.3d 1102, 1109 (D.C. Cir. 2014). It is thus the Secretary, not respondents, that is asking this Court to alter the long-settled status quo.

B. Notice and Comment Assures Providers the Predictability and Accountability that Congress Commanded.

The Court should decline the Secretary's invitation to curtail the Medicare Act's notice-and-

comment requirements not only because the statute plainly compels that result, but also because those requirements are essential to the effective administration of the PPS system. As explained, the whole point of the prospective system is to incentivize providers to be more efficient and cost-effective. To achieve that goal, providers must know not just what the annual rate will be, but how the Secretary will calculate the myriad adjustments and alterations the Medicare Act contemplates to those rates. That is precisely why Congress has mandated notice and comment for *every* "rule, requirement, or other statement of policy ... that establishes or changes a substantive legal standard governing ... the payment for services." 42 U.S.C. §1395hh(a)(2). Without the fair and advance notice that notice-and-comment rulemaking provides on *all* payment policies, providers will not have the ability to fully take into account what "the payment for services" will be when planning for the upcoming fiscal year.

After all, hospitals have to budget for each fiscal year well in advance. Indeed, *amici* begin that process (at least) as soon as the Secretary releases the proposed annual rule for each fiscal year, which typically happens in late April or early May. *See* BIO.Add.1a-3a. While neither the proposed rule nor the final rule can tell hospitals what their actual DSH adjustments will be (those cannot be calculated until after the data from the coming year is available to input), knowing how those adjustments will be calculated allows hospitals to project their DSH adjustments with a fair amount of confidence. And having advance notice of that calculation and other payment information not only ensures that hospitals

can take that data into account *before* their budgets, forecasts, and management for the coming year are finalized; it also ensures that hospitals and other members of the regulated community will have time to provide meaningful feedback on proposed changes to the Secretary's payment methodology before it is too late for the Secretary to reverse course. Congress plainly envisioned this back-and-forth dialogue, *see, e.g.*, H.R. Rep. No. 100-391(I), at 430, and only notice-and-comment rulemaking ensures that it can occur on a timeline consistent with the objectives that a *prospective* payment system is designed to achieve.

That back and forth is particularly critical "[g]iven the enormity of the Medicare program," as even "seemingly modest" tweaks to the Secretary's calculation methodologies can "represent substantial sums of money." *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1010 (D.C. Cir. 1999); *cf. Allina I*, 746 F.3d at 1105 ("Although ostensibly only a detail, the financial impact is apparently substantial, costing the hospitals hundreds of millions of dollars."). This is a case in point: In requesting review here, the Secretary estimated that the issue underlying this case "affects between $3 and $4 billion in Medicare funding." Pet.14. It affects hospitals, moreover, in one of the most critical areas, as the whole point of the DSH adjustment is to enable and incentivize hospitals to serve a "disproportionate share" of low-income patients. *See infra* Part II.A-B. And thousands of hospitals in virtually every state do just that.[2]

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[2] Because Maryland has a "unique all-payer rate-setting system for hospital services" that operates outside of the PPS system, its hospitals do not receive DSH adjustments. *See*

For example, based on recently filed 2017 Medicare cost reports and excluding managed care, 79.42% of acute care patient days are Medicare and Medicaid days at Lourdes Medical Center of Burlington County in Willingboro, New Jersey (formerly known as Rancocas Hospital; part of the Trinity Health hospital network and an *amicus* here). The numbers for other hospitals across the country reflect a similar commitment to providing services to those in need: 71.40% at Marian Community Hospital in Carbondale, Pennsylvania; 65.64% at North Colorado Medical Center in Greeley, Colorado; 62.63% at Banner University Medical Center Phoenix (formerly Banner Good Samaritan Medical Center) in Phoenix, Arizona; 52.50% at UMass Memorial HealthAlliance-Clinton Hospital with campuses in Clinton, Fitchburg, and Leominster, Massachusetts; 47.55% at Northern Light Mercy Hospital in Portland, Maine; 44.65% at Mercy Hospital in Miami, Florida; and 42.93% at Samaritan Hospital in Troy, New York.

As with many aspects of Medicare, moreover, a hospital's DSH adjustment has consequences beyond the DSH adjustment itself. For instance, the size of its DSH percentage also determines whether a hospital may participate in the 340B Drug Pricing Program under the Public Health Service Act, which provides qualifying hospitals with substantial discounts on outpatient drugs. *See* 42 U.S.C. §256b(a)(4)(L). For many *amici*, how Part C days are treated in calculating the DSH adjustment will make the difference in whether they are eligible for the 340B

Maryland All-Payer Model, CMS, https://bit.ly/2Bj3XbK (last visited Dec. 20, 2018). But hospitals in all other 49 states do.

Program in a given year. Savings under the 340B Program are often substantial: "DSH hospitals ... reported saving a median of $5 million to $10 million from 340B discounts in [FY 2017]," and 20 percent of those hospitals "reported more than $25 million in savings." *See* 340B Health, ***Evaluating 340B Hospital Savings and Their Use in Serving Low-Income and Rural Patients: Results from 340B Health's 2017 Annual Survey*** 4 (June 2018), https://bit.ly/2rGVyKK. Whether those considerable savings will be available is precisely the kind of information that Congress wanted hospitals to know ***before*** they have to finalize their pricing, cost allocations, and budget projections for the coming fiscal year and make all manner of forward-looking decisions on issues such as personnel recruitment and retention, capital expenditures, and building renovations.

Finally, while the Secretary seeks refuge in the complexity of the Medicare regime, that complexity only underscores the need for the fair notice and transparency that notice-and-comment engenders. The regulated community is by far the best positioned to understand the real-world impact of alterations to the Secretary's payment methodology. Requiring the Secretary not only to explain those changes in advance, but to consider and respond to the comments they prompt, is the best way to ensure that there is at least ***some*** measure of oversight in this admittedly complex area. That oversight is particularly critical because all too often "[t]he only thing that" seems to explain the Secretary's payment methodologies "is [his] apparent policy of paying out as little money as possible." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 20

n.1 (D.C. Cir. 2011) (Kavanaugh, J., concurring). Indeed, the notice-and-comment process once revealed that the Secretary had deprived hospitals of more than $1 billion over the course of a decade due to a simple math error—yet the Secretary would not even correct the error *prospectively* until the D.C. Circuit ordered him to do so. *See Cape Cod Hosp.*, 630 F.3d at 216. Particularly in a world with considerable deference to the Secretary's substantive decisions, meaningful procedural constraints can make all the difference.

* * *

In sum, Congress' decision to impose a more demanding notice-and-comment requirement under the Medicare Act than under the Administrative Procedure Act makes perfect sense. Meaningful advance notice of and dialogue about how payments and adjustments will be calculated is critical to ensuring that the PPS system achieves its intended ends. Moreover, requiring notice and comment for all changes to how payments and adjustments will be calculated imposes little additional administrative burden because the Secretary is already statutorily obligated to undertake a comprehensive notice-and-comment rulemaking addressing comprehensive PPS rates and adjustments each fiscal year. And the Secretary has long used that process, not other less formal tools, to address changes to the DSH adjustment. Thus, to the extent the Secretary now contends that such changes do not have to be done through notice-and-comment rulemaking, that approach is flatly at odds with the Secretary's long history of using notice and comment in precisely that way. Accordingly, this Court should affirm what is

clear on the face of the statute. If the Secretary wants to "establish[] or change[] a substantive legal standard governing ... the payment for services," 42 U.S.C. §1395hh(a)(2), then the Secretary must do what he has been doing for decades: use notice-and-comment rulemaking.

II. The Tortured History Of This Case Underscores The Critical Role That Notice-And-Comment Rulemaking Serves.

Notice-and-comment rulemaking is particularly critical in the context of the DSH adjustment because the Secretary has an unfortunate history of trying to subvert Congress' intent and systematically reduce hospitals' DSH adjustments. *See Jewish Hosp., Inc. v. Sec'y of Health & Human Servs.*, 19 F.3d 270, 276 (6th Cir. 1994) (finding "credible and compelling" evidence of the agency's "hostil[ity] to the concept of [the] disproportionate share adjustment"). Indeed, the questions presented in this case arose only because the Secretary's efforts to alter how the DSH fractions would be calculated *sub silentio* failed, leaving the agency with the reinstated baseline standard in effect before 2004, which did not allow the Secretary to employ his now-preferred calculation methodology. While that history explains why the Secretary now finds himself advancing a position that is squarely at odds with how the agency has long administered both the Medicare Act generally and the DSH adjustment specifically, it certainly does not justify his effort to free himself from the constraints of notice-and-comment rulemaking. To the contrary, the tortured history behind this case underscores the critical role that notice-and-comment rulemaking plays in holding

the Secretary accountable in this exceedingly complex area.

A. The Secretary Has a Long History of Trying to Subvert the DSH Adjustment.

When Congress shifted to the prospective payment system in 1983, it recognized that low-income patients are, as a class, more costly to treat. Among other things, many low-income patients lack access to preventative medicine and suffer from poor nutrition, and hospitalization of low-income patients often results in the discovery of (and need to treat) health issues beyond those that prompted hospitalization (and thus beyond the reimbursement that the hospital will receive for treating the patient). As a result, hospitals that (like *amici*) treat a high percentage of low-income patients typically have higher-than-average costs per case for all patients (including patients who are not low-income). *See* H.R. Rep. No. 99-241(I), at 16 (1985), *reprinted in* 1986 U.S.C.C.A.N 579, 594 (finding that hospitals that treat a large proportion of low-income patients overall tend to incur higher costs per case due, in part, to the specialized services that they provide and other structural characteristics of these hospitals).

To ensure that hospitals would be able and incentivized to continue to provide care to those in need, Congress instructed the Secretary to make "exceptions and adjustments" to the new fixed rates "to take into account the special needs ... of public or other hospitals that serve a significantly disproportionate number of patients who have low income or are entitled to benefits under part A of" Medicare. 42 U.S.C. §1395ww(d)(5)(C)(i) (1983). "The

'overriding intent' of Congress in establishing the DSH reimbursement was to 'supplement the prospective payment system payments of hospitals serving low-income persons[,]' ... 'because those patients historically require comparatively greater resources in their care.'" *Alhambra Hosp. v. Thompson*, 259 F.3d 1071, 1075-76 (9th Cir. 2001).

Notwithstanding that mandate, the Secretary refused to make any such exceptions or adjustments, insisting they were not "warranted." 49 Fed. Reg. 234, 276 (Jan. 3, 1984). The next year, Congress once again attempted to force the Secretary to act, this time mandating that the Secretary at least adopt a definition for determining whether a hospital serves a significantly disproportionate number of low-income patients. *See* Deficit Reduction Act of 1984, Pub. L. No. 98-369, §2315(h), 98 Stat. 494, 1080. The Secretary once again did nothing. A number of hospitals then brought suit to compel the Secretary to comply with Congress' mandates. After the court ordered "the Secretary to publish [a] definition ... on or before December 31, 1985," *Samaritan Health Ctr. v. Heckler*, 636 F. Supp. 503, 519 (D.D.C. 1985), the Secretary finally relented but adopted an unreasonably narrow definition of a disproportionate share hospital that would have included "only 1% of the hospital beds in the United States and only a handful of hospitals located in urban areas." *Samaritan Health Ctr. v. Bowen*, 646 F. Supp. 343, 346 (D.D.C. 1986); 50 Fed. Reg. 53,398, 53,398-400 (Dec. 31, 1985).

At that point, Congress took matters into its own hands and established its own statutory formula to

ensure that hospitals are adequately compensated for the services they provide to low-income patients. To that end, Congress instructed the Secretary to increase each qualifying hospital's annual reimbursement based on the extent to which the hospital's "disproportionate patient percentage" exceeds a certain threshold. Congress defined that percentage as the sum of two fractions:

> (I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter and were entitled to supplementary security income benefits (excluding any State supplementation) under subchapter XVI of this chapter, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter, and
>
> (II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, but who were not entitled to benefits under part A of this subchapter, and the denominator of which is the total number of the hospital's patient days for such period.

42 U.S.C. §1395ww(d)(5)(F)(vi).

In essence, the first fraction (known in the regulated community as the Medicare fraction) asks, out of all days spent treating patients "entitled" to benefits under Part A of Medicare, what proportion is attributable to patients who are also "entitled" to supplemental security income ("SSI") benefits. In other words, the Medicare fraction uses entitlement to SSI benefits as a proxy for whether patients whose services are covered by Part A are low-income patients. The second fraction (known as the Medicaid fraction) asks, out of all patient days *total*, what proportion is attributable to patients who are "eligible" for Medicaid *but not* "entitled" to benefits under Part A. In other words, the Medicaid fraction uses eligibility for Medicaid as a proxy for whether patients are low-income, but excludes days attributable to patients who are both "eligible" for Medicaid and "entitled" to benefits under Part A, thereby ensuring that patient days covered by Part A are not double-counted in the two fractions. Combined, Congress intended this percentage to serve as a "proxy" for the number of low-income patients a hospital serves. *Ne. Hosp.*, 657 F.3d at 3 (citing H.R. Rep. No. 99-241(I), at 17).

Each fiscal year, a hospital's Medicare fraction is calculated by the Secretary, and its Medicaid fraction is calculated by one of the insurance companies that serve as audit agents for the Secretary (now known as "Medicare Administrative Contractors," and formerly known as "fiscal intermediaries"). Because the sum of the fractions is used as a multiplier to calculate a hospital's DSH adjustment, the greater the sum (and the greater each fraction), the greater the DSH adjustment.

The Secretary's reluctance to compensate DSH hospitals as Congress contemplated did not wane with the codification of the DSH adjustment formula. Shortly after Congress enacted that formula, the Secretary promulgated regulations that systematically reduced DSH adjustments by refusing to treat patients as "eligible" for Medicaid unless Medicaid actually paid for the specific services at issue. *See* 51 Fed. Reg. at 16,777. That regulation was challenged throughout the country, and court after court invalidated it as foreclosed by the plain text of the statute. *See, e.g.*, *Cabell Hunting Hosp., Inc. v. Shalala*, 101 F.3d 984, 988 (4th Cir. 1996); *Legacy Emanuel Hosp. & Health Ctr. v. Shalala*, 97 F.3d 1261, 1265 (9th Cir. 1996); *Deaconess Health Servs. Corp. v. Shalala*, 83 F.3d 1041, 1041 (8th Cir. 1996) (per curiam), *aff'g* 912 F. Supp. 438 (E.D. Mo. 1995); *Jewish Hosp. Inc. v. Sec'y of Health & Human Servs.*, 19 F.3d 270, 275 (6th Cir. 1994). Courts likewise concluded that the Secretary's effort to artificially decrease each hospital's Medicaid fraction was inconsistent with Congress' "overarching intent to compensate hospitals for serving low-income people" through the DSH adjustment. *Legacy Emanuel*, 97 F.3d at 1266; *see also, e.g.*, *Jewish Hosp.*, 19 F.3d at 275.

After this string of losses, the Secretary relented. But the Secretary soon began devising other methods of systematically decreasing the DSH adjustment to the financial detriment of hospitals serving those in need.

B. This Case Arises Out of a Failed Effort to Decrease DSH Adjustments *Sub Silentio*.

This case arises out of one such effort, involving beneficiaries of Part C of Medicare. Individuals who are eligible to participate in Medicare can obtain insurance under different "parts" of the program. Medicare Part A provides Medicare enrollees with government-administered health insurance through which the government makes direct payments to hospitals for healthcare services provided. *See* 42 U.S.C. §§1395c-1395i-5. Medicare Part C, by contrast, provides enrollees with government-subsidized enrollment in private insurance plans. *See id.* §§1395w-21-1395w-29.

Because Medicare Part A will not pay for services provided to patients enrolled in Medicare Part C, the Secretary traditionally treated such patients as not "entitled to benefits under Part A." *See Ne. Hosp.*, 657 F.3d at 15-17. This meant that patient days attributable to such patients were *not* included in the Medicare fraction (because both the numerator and the denominator of that fraction include only days for patients "entitled to benefits under Part A"), but *were* included in the numerator of the Medicaid fraction if they were eligible for Medicaid (because the numerator includes days for patients who were eligible for Medicaid benefits but *not* "entitled to benefits under Part A"), as well as in the denominator of the Medicaid fraction (which includes all patients). That practice was consistent with a rule enacted through notice and comment back in 1986 when the DSH adjustment was first codified that expressly included in the Medicare statute only patient days

actually "covered" by Part A. *See* 51 Fed. Reg. at 16,777; 42 C.F.R. §412.106(b)(2)(i) (2003).

In the proposed rulemaking for FY 2004, the Secretary addressed the calculation of the DSH adjustment (as the Secretary had done almost every year since 1986 and would continue to do almost every one of the next 15 years). *See* 68 Fed. Reg. 27,154, 27,201-08 (May 19, 2003). And, as to the treatment of Part C patients (also then known as "M+C patients"), that rulemaking "propos[ed] to clarify that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should *not* be included in the *Medicare* fraction of the DSH patient percentage," but "*should* be included in the count of total patient days in the *Medicaid* fraction (the denominator), and the patient's days for the M+C beneficiary who is also eligible for Medicaid would be included in the numerator of the Medicaid fraction." *Id.* at 27,208 (emphases added). In other words, the Secretary proposed to reaffirm his longstanding practice of treating patients who receive coverage under Part C as not "entitled to benefits under Part A."

The Secretary did not end up promulgating this (or any other) rule governing the treatment of Part C patients in the final rule for FY 2004. *See* 68 Fed. Reg. 45,346, 45,422 (Aug. 1, 2003). Instead, the Secretary put the issue off. *See* 69 Fed. Reg. 28,196, 28,286 (May 18, 2004). When the Secretary released the FY 2005 Rule, however, the agency did an about-face. Instead of adopting the position that had been proposed in the FY 2004 rulemaking and followed for years, the Secretary announced that, henceforth, Part C days

"should be *included* in the *Medicare* fraction of the DSH calculation," and *excluded* from the *Medicaid* fraction—*i.e.*, exactly the opposite of what the Secretary had proposed in 2003. 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004) (emphases added). In support of this abrupt 180-degree change of course, the Secretary offered only the feeble explanation that even though Part A will not pay for inpatient services provided to someone who has elected coverage under Part C, Part C beneficiaries "are still, in some sense, entitled to benefits under Medicare Part A." *Id.*

The Secretary did not acknowledge the massive consequences of this change in the FY 2005 rulemaking, but its ultimate impact was to "decrease[] the DSH adjustment that hospitals receive" to the tune of "hundreds of millions of dollars." *Ne. Hosp.*, 657 F.3d at 5.[3] Indeed, even that estimate ultimately proved far too conservative, as the government has now estimated that this issue "affects between $3 and $4 billion in Medicare funding." Pet.14.[4]

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[3] As the D.C. Circuit explained, *including* Part C patient days in the Medicare fraction "dilutes th[at] fraction because M+C enrollees are less likely to qualify for SSI benefits than non-M+C enrollees," meaning their inclusion will increase the denominator far more than the numerator. *Ne. Hosp.*, 657 F.3d at 5. Conversely, *excluding* such days from Medicaid fraction dilutes that fraction because "counting M+C patients among patients 'entitled to benefits under Part A' decreases the numerator of the fraction (all patients 'eligible for [Medicaid]' *but not* 'entitled to benefits under Part A') and has no effect on the denominator ('total number of patient[s]')." *Id.* As a result, each fraction, as well as their sum, is smaller, producing a smaller DSH adjustment.

[4] The government has conveniently re-characterized the financial significance of this litigation based on whether it was

C. The Secretary's Failure to Provide *Effective* Notice and Comment in 2004 Does Not Entitle Him to Effectuate His Preferred Payment Policy Unilaterally.

As then-Judge Kavanaugh explained when the FY 2005 Rule was first challenged in court, the rule should have failed under the plain language of the Medicare Act because a patient cannot "be both enrolled in Part C and entitled to Part A benefits *for the same day*." *Ne. Hosp.*, 657 F.3d at 19 (Kavanaugh, J., concurring). "Medicare beneficiaries must choose between government-subsidized private insurance plans under Part C and government-administered insurance under Part A," and "after they choose, they are obviously not entitled on the same 'patient day' to benefits from both kinds of plans." *Id.* at 18. Nonetheless, a two-judge majority in the *Northeast Hospital* case found that the phrase "entitled to benefits under Part A" left a gap for the Secretary to fill. 657 F.3d at 5, 11-13.

The majority decided not to reach the question of whether the Secretary's new rule could survive, however, as *Northeast Hospital* involved only an effort to apply the rule *retroactively*. And on that question, the judges were unanimous: The Secretary could not

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trying to get the Court's attention (as in its petition) or trying to minimize the impact of its sudden change in position (as in its merits brief). In reality, the financial impact is and always has been substantial, which only underscores that the Secretary's change in position was indeed a "rule, requirement, or other statement of policy ... that establishe[d] or change[d] a substantive legal standard governing ... the payment for services," and thus required notice-and-comment rulemaking. 42 U.S.C. §1395hh(a)(2).

apply this new rule to fiscal years past. While the Secretary argued (as he does again here) that the rule "merely confirmed [the Secretary's] longstanding view" that Part C beneficiaries "are still 'entitled to benefits under Part A,'" the court found precisely the opposite: Before 2004, "the Secretary routinely *excluded* M+C days from the Medicare fraction." *Id.* at 14-15; *see also Allina I*, 746 F.3d at 1106 ("Prior to 2003, the Secretary treated Part C patients as *not* entitled to benefits under Part A.").

Indeed, until 2007 (*i.e.*, a decade after Medicare Part C was enacted), the Secretary had not even asked all hospitals to provide the data that would have been needed to include those days in the fraction. In fact, the Secretary affirmatively told hospitals in 1998—*i.e.*, the year after Congress enacted Medicare Part C—"*not* to submit information that [CMS would have] needed to count M+C days in the Medicare fraction." *See Ne. Hosp.*, 657 F.3d at 15 (citing Program Memorandum (Intermediaries), HCFA Pub. 60A, Transmittal No. A–98–21 (July 1, 1998)). As the D.C. Circuit thus concluded, there can be no serious dispute that the Secretary was excluding Part C days from the Medicare fraction before the FY 2005 Rule tried to change course, as the Secretary did not even have the data necessary to include them. Indeed, the Secretary *still* does not have the data for FY 2005 and thus could not apply the FY 2005 Rule consistently across the years in question. Because of this clear prior practice, the court concluded that "the Secretary's present interpretation, which marks a substantive departure from [his] prior practice of excluding M+C days from

the Medicare fraction, may not be retroactively applied to fiscal years 1999-2002." *Id.* at 17.[5]

That left the question of whether the Secretary could apply the FY 2005 Rule going forward. And on that question, the D.C. Circuit said no as well, invalidating the rule on the ground that "the Secretary's final rule was not a logical outgrowth of the proposed rule." *Allina I*, 746 F.3d at 1109. As the court recognized, "[t]here is nothing in the text of the notice[] ... to suggest that the Secretary was thinking of reconsidering a longstanding practice." *Id.* at 1108. To the contrary, "the notice indicated that 'there should not be a major impact associated with this change,'" which certainly would not be the case had the Secretary been considering a reversal of course that would cost hospitals billions of dollars. *Id.* (citing 68 Fed. Reg. at 27,416). The court thus concluded that "a reasonable member of the regulated class—even a good lawyer—[would not] anticipate that such a volte-face with enormous financial implications would follow the Secretary's proposed rule." *Id.* at 1109; *see also id.* at 1108 ("[A] party reviewing the Secretary's notice of proposed rulemaking understandably would have assumed that the Secretary was proposing to 'clarify' a then-existing policy, *i.e.*, one of excluding Part C days from the Medicare fraction and including them in the Medicaid fraction.").

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[5] Contrary to the Secretary's contention that "the agency never promulgated its pre-2004 practice through notice-and-comment rulemaking," as explained, *see supra* pp.24-25, the Secretary had long had in place a rule under which the DSH Medicare fraction included only patient days that were actually "covered" by Medicare Part A.

By now acutely aware that a significant amount of money was at stake (although still not acknowledging that impact—or even the change itself—to the regulated community or the courts), the Secretary insisted on taking another stab at converting patient days for which Medicare Part A will not pay into days on which the patient nonetheless is "entitled to benefits under Part A." And the Secretary did so the same way the Secretary did in 2003: by utilizing the notice-and-comment rulemaking process. In 2013, the Secretary proposed that, in its final rule for FY 2014, it would declare Part C patients "entitled to benefits under Part A." 78 Fed. Reg. at 27,578. And later that same year, the Secretary did indeed promulgate that rule in its final rule for FY 2014. 78 Fed. Reg. at 50,614-15, 50,620. The Secretary chose not even to try to invoke its limited retroactive rulemaking authority under §1395hh(e), leaving him with no rule that allowed him to treat patients whose services were covered by Part C as "entitled to benefits under Part A" when calculating hospitals' Medicare fractions for years pre-dating the FY 2014 Rule.

Of course, there was an easy solution to this conundrum: follow the *true* longstanding practice and policy of *excluding* Part C days from the Part-A-entitled days in the Medicare fraction, just as the Secretary had done for years before trying to abruptly change course in 2004. Indeed, that was the only course consistent with the concerns animating *Northeast Hospital* and *Allina I*, as the whole point of those cases was to prevent the Secretary from effectuating this massive policy change in how DSH adjustments are calculated without giving hospitals fair notice. *See Allina I*, 746 F.3d at 1108

(admonishing Secretary that "agencies may not 'pull a surprise switcheroo on regulated entities'"). But the Secretary could not let it go. In June 2014, the Secretary published a spreadsheet containing the Medicare fractions for every hospital in the nation, to be used in calculating each hospital's FY 2012 DSH adjustment. *See* Pet.App.5a-6a, 24a, 32a & n.2; FY 2012 SSI Ratios, CMS, https://go.cms.gov/2CmkPju (last visited Dec. 20, 2018). And the spreadsheet summarily declared, without explanation, that the Part C days were included in these Medicare fractions. In other words, the Secretary attempted to impose by fiat, rather than through notice and comment or under §1395hh(e), exactly the same "substantive departure from her prior practice of excluding M+C days from the Medicare fraction," *Ne. Hosp.*, 657 F.3d at 17, that the FY 2005 Rule had failed to achieve.

* * *

As the foregoing illustrates, this case does not arise out of an effort to force the Secretary to use notice and comment in a novel, or even unusual, context. To the contrary, the Secretary himself voluntarily used notice-and-comment rulemaking each prior time he sought to alter (or, as he would put it, "clarify") his policy for calculating the fractions used to determine a hospital's DSH adjustment—first in 2004, and then again in 2013. Indeed, as explained, *supra* Part I.A, the Secretary routinely uses notice-and-comment rulemaking for all manner of issues relating to the calculation of the DSH payment adjustment. The Secretary departed from that practice for the fiscal year at issue here only because the agency's effort to effectuate its preferred policy

through the 2004 rulemaking *failed*, on account of its failure to provide the regulated community with the notice necessary to enable it to comment, and the Secretary could not apply his FY 2014 Rule retroactively.

This is thus the very last case in which the Court should free the Secretary from the constraints of notice-and-comment rulemaking, as the Secretary abandoned that process only in a last-ditch effort to salvage a failed rulemaking and circumvent the statutory constraints on his authority to make retroactive rules. Not only does that confirm that the decision below should be affirmed regardless of how the Court answers the first question presented. *See* 42 U.S.C. 1395hh(a)(2). It also confirms that requiring the Secretary to employ notice-and-comment before effectuating a policy change of this magnitude would not impose any serious or novel burden—let alone "cripple effective administration of the Medicare program." Pet'r.Br.18. Instead, as Congress recognized in both Section 1395hh(a)(2) and Section 1395hh(a)(4), notice and comment is the best antidote to the Secretary's seeming inability to resist the temptation to try to effectuate billion-dollar changes to the Medicare payment scheme *sub silentio*.

CONCLUSION

For the foregoing reasons, this Court should affirm the judgment of the D.C. Circuit.

Respectfully submitted,

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December 20, 2018

APPENDIX

APPENDIX OF AMICI CURIAE

Albany Memorial Hospital, *Provider No. 33-0003 (New York)*

Banner Baywood Medical Center, *Provider No. 03-0088 (Arizona)*

Banner Casa Grande Medical Center (formerly Casa Grande Regional Medical Center), *Provider No. 03-0016 (Arizona)*

Banner Del E. Webb Medical Center, *Provider No. 03-0093 (Arizona)*

Banner Desert Medical Center, *Provider No. 03-0065 (Arizona)*

Banner Estrella Medical Center, *Provider No. 03-0115 (Arizona)*

Banner Gateway Medical Center, *Provider No. 03-0122 (Arizona)*

Banner Goldfield Medical Center, *Provider No. 03-0134 (Arizona)*

Banner Mesa Lutheran Medical Center (formerly Mesa Lutheran Medical Center), *Provider No. 03-0018 (Arizona)*

Banner Thunderbird Medical Center, *Provider No. 03-0089 (Arizona)*

Banner University Medical Center Phoenix (formerly Banner Good Samaritan Medical Center), *Provider No. 03-0002 (Arizona)*

Berkshire Medical Center, *Provider No. 22-0046 (Massachusetts)*

Bethesda Hospital, *Provider No. 36-0179 (Ohio)*

Central Washington Hospital, *Provider No. 50-0151 (Washington)*

CHI Health Creighton University Medical Center - Bergan Mercy (formerly Bergan Mercy Medical Center), *Provider No. 28-0060 (Nebraska)*

CHI Health Creighton University Medical Center - University Campus, *Provider No. 28-0030 (Nebraska)*

CHI Health Good Samaritan, *Provider No. 28-0009 (Nebraska)*

CHI Health Immanuel, *Provider No. 28-0081 (Nebraska)*

CHI Health Mercy Council Bluffs, *Provider No. 16-0028 (Iowa)*

CHI Saint Alexius Health Bismarck, *Provider No. 22-0074 (North Dakota)*

CHI Health Saint Elizabeth, *Provider No. 28-0020 (Nebraska)*

CHI Health Saint Francis, *Provider No. 28-0023 (Nebraska)*

CHI Saint Luke's Health - Baylor St. Luke's Medical Center (formerly Saint Luke's Episcopal Hospital), *Provider No. 45-0193 (Texas)*

CHI Saint Luke's Health - Sugar Land Hospital, *Provider No. 67-0053 (Texas)*

CHI Saint Luke's Health - The Vintage Hospital, *Provider No. 57-0075 (Texas)*

CHI Saint Luke's Health - The Woodlands Hospital, *Provider No. 45-0862 (Texas)*

CHI Saint Vincent Infirmary Medical Center, *Provider No. 04-0007 (Arkansas)*

CHI Saint Vincent North, *Provider No. 04-0137 (Arkansas)*

The Christ Hospital, *Provider No. 36-0163 (Ohio)*

Flaget Memorial Hospital, *Provider No. 18-0025 (Kentucky)*

Good Samaritan Hospital, *Provider No. 36-0134 (Ohio)*

Harrison Medical Center, *Provider No. 50-0039 (Washington)*

Heywood Hospital, *Provider No. 22-0095 (Massachusetts)*

Highline Medical Center - CHI Franciscan Health, *Provider No. 50-0011 (Washington)*

Jewish Hospital & Saint Mary's HealthCare, *Provider No. 18-0040 (Kentucky)*

Jewish Hospital Shelbyville, *Provider No. 18-0016 (Kentucky)*

Lourdes Medical Center of Burlington County (formerly Rancocas Hospital), *Provider No. 31-0061 (New Jersey)*

Marian Community Hospital, *Provider No. 39-0095 (Pennsylvania)*

McKee Medical Center, *Provider No. 06-0030 (Colorado)*

Memorial Hermann Hospital System, *Provider No. 45-0184 (Texas)*

Memorial Hermann Katy Hospital, *Provider No. 45-0847 (Texas)*

Memorial Hermann Memorial City Medical Center, *Provider No. 45-0610 (Texas)*

Memorial Hermann Northeast Hospital, *Provider No. 45-0684 (Texas)*

Memorial Hermann Sugar Land Hospital, *Provider No. 45-0848 (Texas)*

Memorial Hermann Texas Medical Center, *Provider No. 45-0068 (Texas)*

Mercy Catholic Medical Center, Provider No. 39-0156 (Pennsylvania)

Mercy Hospital - Miami, *Provider No. 10-0061 (Florida)*

Mercy Medical Center - Springfield, *Provider No. 22-0066 (Massachusetts)*

Mercy Medical Center - Williston, *Provider No. 35-0017 (North Dakota)*

Mercy Medical Center - Roseburg, *Provider No. 38-0027 (Oregon)*

Mercy Medical Center - Des Moines, *Provider No. 16-0083 (Iowa)*

Nazareth Hospital, *Provider No. 39-0204 (Pennsylvania)*

North Colorado Medical Center, *Provider No. 06-0001 (Colorado)*

Our Lady of Lourdes Medical Center, *Provider No. 31-0029 (New Jersey)*

Northern Light Mercy Hospital, *Provider No. 20-0008 (Maine)*

Saint Clare Hospital, *Provider No. 50-0021 (Washington)*

Saint Francis Hospital - Federal Way, *Provider No. 50-0141 (Washington)*

Saint Francis Hospital - Wilmington, *Provider No. 08-0003 (Delaware)*

Saint Francis Medical Center, *Provider No. 31-0021 (New Jersey)*

Saint Joseph East, *Provider No. 18-0143 (Kentucky)*

Saint Joseph Hospital, *Provider No. 18-0010 (Kentucky)*

Saint Joseph London Hospital, *Provider No. 18-0011 (Kentucky)*

Saint Joseph Medical Center, *Provider No. 50-0108 (Washington)*

Saint Mary's Health Care System, Inc., *Provider No. 11-0006 (Georgia)*

Saint Michael's Medical Center, *Provider No. 31-0096 (New Jersey)*

Saint Peter's Hospital, *Provider No. 33-0057 (New York)*

Samaritan Hospital, *Provider No. 33-0180 (New York)*

Seton Health, *Provider No. 33-0232 (New York)*

Signature Healthcare Brockton Hospital, *Provider No. 22-0052 (Massachusetts)*

South County Hospital, *Provider No. 41-0008 (Rhode Island)*

Southwest Consulting Associates

Suburban Community Hospital (formerly Mercy Suburban Hospital), *Provider No. 39-0116 (Pennsylvania)*

University of Arkansas Medical Sciences Medical Center, *Provider No. 04-0016 (Arkansas)*

UMass Memorial - HealthAlliance Hospital, *Provider No. 22-0001 (Massachusetts)*

UMass Memorial HealthAlliance-Clinton Hospital, *Provider No. 22-0058 (Massachusetts)*

UMass Memorial - Marlborough Hospital, *Provider No. 22-0049 (Massachusetts)*

UMass Memorial Medical Center, *Provider No. 22-0163 (Massachusetts)*

Vanderbilt University Medical Center, *Provider No. 44-0039 (Tennessee)*